# PURETECH

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# PureTech Year End Update and Outlook for 2024

December 20, 2023 RNS Number : 3812X PureTech Health PLC 20 December 2023

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# PureTech Health plc

PureTech Year End Update and Outlook for 2024

Strong strategic and clinical progress in 2023, with multiple catalysts expected in 2024

Launching of two new Founded Entities to advance certain programs from the Wholly Owned Pipeline

Robust balance sheet position with estimated Consolidated Cash, Cash Equivalents and Short-Term Investments at year end of approximately \$320 million<sup>1</sup>, extends operational runway guidance into 2027

<u>PureTech Health plc</u> (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to changing the lives of patients with devastating diseases, today reports on the key progress made across its Wholly Owned Programs<sup>2</sup> and Founded Entities<sup>3</sup> in 2023, announces two new Founded Entities and provides an update on cash and operational runway guidance.

# Key Highlights:

- Strong progress in 2023 included the successful LYT-300 clinical trial of acute anxiety in healthy adults and initial data from ongoing clinical trials of LYT-200 in solid tumors and acute myeloid leukemia, along with Royalty Pharma deal of up to \$500M, as well as clinical and regulatory advances across multiple Wholly Owned Programs and Founded Entities.
- PureTech continues to build and will further expand its Wholly Owned Pipeline focus in pulmonary and rare diseases. Certain Glyph<sup>TM</sup> intellectual property will remain at PureTech. Key catalysts expected in 2024 include results from idiopathic pulmonary fibrosis (IPF) late-stage trial of LYT-100 in Q4 2024.
- New clinical-stage neuroscience Founded Entity: <u>Seaport Therapeutics</u> will advance certain central nervous system (CNS) programs and relevant Glyph intellectual property. Rapid growth of neuroscience pipeline, powered by Glyph platform, including new therapeutic candidate announced today (LYT-320), and initiations of two clinical trials in 2024 (LYT-300 and LYT-310).
- New clinical-stage oncology Founded Entity: <u>Gallop Oncology</u> to advance LYT-200 and other galectin-9
  intellectual property; additional results from clinical trials in leukemia and solid tumors expected in 2024.
- Robust balance sheet position with estimated Consolidated Cash, Cash Equivalents and Short-Term
   Investments at year end of approximately \$320 million<sup>1</sup>, extends operational runway guidance into 2027 based on the Company's strategic operating plan.

The PureTech Board may declare special dividends and/or share buybacks as part of an overall returns strategy.

Daphne Zohar, Founder and Chief Executive Officer of PureTech, commented: "PureTech has had a particularly productive year. One of the advantages of the hub-and-spoke model we pioneered is that it has enabled us to build an exciting pipeline of new medicines poised for tremendous growth, without diluting our shareholders in almost seven years. Our Founded Entities are a significant source of value to us, and we have generated over \$800 million in non-dilutive proceeds to advance our pipeline and growth since 2020.

"A good example of how our successful model has funded our pipeline and operations is our strategic deal with Royalty Pharma acquiring an interest in our royalty in KarXT for up to \$500 million, which provided us with upfront non-dilutive capital and significant upside based on Karuna's future regulatory and commercial successes.

"I'm also proud of our track record which includes 80 percent<sup>4</sup> success across clinical trials, with a probability of clinical success that is six times better than the industry average<sup>5</sup>.

"Advancing programs to a key value inflection point before determining the most expedient and cost-effective path forward is a hallmark of our hub-and-spoke business model, and we've seen the success of it realized in the U.S. FDA clearance of two medicines, a third that has recently filed for approval, and several additional therapeutic candidates being advanced through late-stage clinical trials. This model allows us to create and advance new medicines in a capital efficient manner. Importantly, the strategic decision announced today to advance certain programs through two new Founded Entities will make it easier for the true value of these programs to be recognized and, as they continue to advance, deliver the greatest value back to our shareholders.

"We are extremely proud of the numerous accomplishments made by our team in 2023 and look forward to a productive and exciting 2024, where we expect to deliver multiple milestones to improve the lives of patients and drive benefit to our shareholders."

Additional highlights and progress include the following:

#### Outlook for 2024, new Founded Entities and execution of corporate strategy

- Building on the success of early studies for LYT-100, and with the important upcoming catalyst for IPF in 2024,
   PureTech will continue to build on its internal expertise in pulmonary and rare diseases and expanding its portfolio in those therapeutic areas. Certain Glyph intellectual property will remain at PureTech.
- PureTech is reinforcing the proven success of its model by adding two new "spokes" to the PureTech "hub." PureTech will be advancing its programs in two important therapeutic areas (neuroscience and oncology respectively) in two new clinical-stage Founded Entities, Seaport Therapeutics and Gallop Oncology.
  - The launch of Seaport Therapeutics will accelerate the development of new neuroscience medicines in areas of high unmet need with the addition of capital partners to bring nearer-term patient benefit. It also builds on the success PureTech has achieved in the neuroscience arena with the same strategy and team at PureTech that invented KarXT. If approved, KarXT will be the third therapeutic candidate to be taken from inception at PureTech to FDA regulatory approval and will represent the first new mechanism of action for patients with schizophrenia in over 50 years.
  - The launch of Gallop Oncology builds on the promising clinical and preclinical data from PureTech's LYT-200 program in solid tumors and hematological malignancies. The development of a novel oncology medicine requires a dedicated effort that is best enabled through a separate Founded Entity and external capital.

#### **Wholly Owned Programs**

o LYT-100 (deupirfenidone) is currently in development for the treatment of IPF, which is a rare, progressive, and

fatal disease. While existing standard-of-care treatments are effective, they cause significant side effects, and as a result, three out of four people living with IPF in the U.S. forego treatment. LYT-100, which has shown 50 percent reduction of the GI and overall adverse events compared to pirfenidone in a head-to-head study, has the potential to both supplant the current standard-of-care treatments and to serve a larger population of patients who are unable to tolerate current therapies.

- o Progressed a Phase 2b dose-ranging trial of LYT-100 in patients with IPF. Topline results are expected in Q4 2024. PureTech plans to pursue a streamlined development program for LYT-100 in IPF and is using the same validated endpoints that have supported past approvals. PureTech believes the results of the ongoing trial, together with an additional registration study in Phase 3, could serve as the basis for registration in the U.S. and other geographies.
- o Presented expanded data at the CHEST Annual Meeting 2023 from a completed trial of LYT-100 in healthy older adults, which informed the two doses selected for the ongoing Phase 2b trial (ELEVATE IPF). In addition to supporting the improved tolerability of LYT-100 versus the FDA-approved dose of pirfenidone, the new data presented supported the selection of a higher dose of LYT-100 with the potential for improved efficacy that is now being evaluated in ELEVATE IPF.

#### **Newly Announced Founded Entities:**

- Seaport Therapeutics:
  - LYT-300 (oral Glyph-allopregnanolone) is an oral prodrug of allopregnanolone, enabled by the Glyph platform, that is currently in development for the treatment of both neuropsychiatric and rare CNS conditions. Allopregnanolone has demonstrated benefit in a range of CNS conditions, but it can only be administered via IV, which has hindered its broad therapeutic use. Using the Glyph platform, LYT-300 retains the activity and potency of endogenous allopregnanolone in an oral form.
    - § Successful topline results from a Phase 2a proof-of-concept trial of LYT-300 using a validated clinical model of anxiety in healthy volunteers were reported recently. Oral administration of LYT-300 achieved the trial's primary endpoint of a statistically significant reduction versus placebo in the increase from baseline to peak levels of the stress hormone salivary cortisol (p=0.0001) with a treatment effect size versus placebo of 0.72, measured by the Cohen's D.
    - § LYT-300 is advancing into a Phase 2 clinical trial for the treatment of Fragile X-associated Tremor/ Ataxia Syndrome (FXTAS), which is a rare neurological disease. A Phase 2 trial is expected to initiate in 2024. PureTech was chosen to receive up to \$11.4 million from the U.S. Department of Defense through a highly competitive grant process to advance LYT-300 in FXTAS.
  - LYT-310 (oral Glyph-cannabidiol [CBD]), is currently in development for the treatment of epilepsies and other neurological indications. A different CBD-based product purified from plant sources, has received regulatory approval in the U.S. and Europe to treat seizures resulting from certain rare conditions, but it requires a large volume of a sesame oil-based formulation, which limits its use in broader indications and age groups.
    - § New today: Preclinical data demonstrated LYT-310 was effective in preventing seizures in the Maximal Electroshock Model (MES), a validated and highly translatable preclinical model considered a gold standard for the assessment of anti-seizure drugs. LYT-310 was tested against various formulations of CBD, including an oral CBD formulation in sesame oil. LYT-310 showed strong anti-seizure protection activity and was shown to be more effective at preventing seizures at a dose three times lower than an oral CBD formulation. Based on the data, LYT-310 has the potential to expand the use of CBD to broader patient populations, particularly in populations and conditions where higher doses are required to achieve a therapeutic effect.
    - § Initiation of a Phase 1 clinical trial of LYT-310 is expected in the first half of 2024.
  - New today: LYT-320 (oral Glyph-agomelatine), was nominated as a new therapeutic candidate powered by PureTech's Glyph platform. A novel prodrug of agomelatine, LYT-320 is in development for the treatment of anxiety and mood disorders. Anxiety disorders affect nearly 30 percent of U.S. adults<sup>6</sup> and are an area of significant unmet need.

- § LYT-320 uses the Glyph platform to bypass first-pass metabolism by the liver and thus has the potential to reduce liver exposure, hepatotoxicity, and the need for liver function monitoring.
- § Selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) are first-line treatments for generalized anxiety disorder (GAD) and depressive disorders but have side effects and efficacy limitations. A major limitation of SSRIs and SNRIs are adverse events such as sexual dysfunction and emotional blunting.
- § Agomelatine acts through a completely different mechanism of action and offers superior overall tolerability for patients compared to standard-of-care. The drug has demonstrated clear human efficacy in multiple studies of GAD where the gold-standard Hamilton Anxiety Rating Scale (HAM-A) was used as the primary endpoint. Agomelatine is approved for major depressive disorder (MDD) in the European Union and for MDD and GAD in Australia. Agomelatine has not been approved in the U.S., offering LYT-320 first-in-class potential for the U.S. market and best-in-class potential in the rest of the world. However, agomelatine is associated with hepatoxicity necessitating extensive liver function monitoring that has held back its use. Agomelatine has very low oral bioavailability (approximately one percent) due to extensive hepatic first-pass metabolism, potentially contributing to hepatoxicity.
- § In multiple *in vivo* studies, LYT-320 showed oral bioavailability and plasma exposures greater than 10-fold higher than orally dosed agomelatine. Exposures comparable to approved therapeutic agomelatine doses could thus be enabled by LYT-320 comprising a reduced dose of agomelatine, which *in silico* modeling using the FDA-licensed DILIsym platform, has projected will greatly reduce the risk of causing clinically significant liver enzyme elevations.
- § Initiation of first-in-human enabling studies is expected in 2024 and LYT-320 is expected to advance into clinical studies in the first half of 2025.

#### Gallop Oncology:

- LYT-200 (anti-galectin-9 mAb) is in development for the treatment of metastatic/locally advanced solid tumors, including head and neck and urothelial cancers, and hematological malignancies, such as acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS). A wide variety of preclinical data support the potential clinical efficacy of LYT-200 and the importance of galectin-9 as a target and suggests a potential opportunity for biomarker development.
  - § Presented data from the ongoing Phase 1 clinical trial of LYT-200 at the ESMO Immuno-Oncology Congress 2023. In the initial results, LYT-200 demonstrated a favorable safety profile in all cohorts, including the monotherapy and combination arms with BeiGene's tislelizumab, and showed disease control and suggestions of initial anti-tumor activity. In the combination arm, 11 patients have been dosed, and all evaluable patients treated so far include four patients with head and neck cancers and two patients with urothelial cancer. In the evaluable patients with head and neck cancers, disease control was observed in three of the four patients, with one patient experiencing a complete response after nine months, one patient with a deepening partial response after eight months, and one patient with disease stabilization at four months so far, with treatment in these patients remains ongoing. The two evaluable patients with urothelial cancer experienced disease stabilization for seven months and three months, so far, and both remain on treatment. The combination arm continues to enroll patients with head and neck and urothelial cancers. Completion of the trial and results are expected by the end of 2024.
- New today: In the ongoing Phase 1b trial evaluating LYT-200 as a single agent in relapsed/refractory AML and MDS patients, three dose escalation cohorts have completed to date at weekly doses of 2 mg/kg (cohort 1), 4 mg/kg (cohort 2) and 7.5 mg/kg (cohort 3). In a heavily pre-treated patient population, the early data demonstrates a favorable safety and tolerability profile of LYT-200 with no dose limiting toxicities. In the first cohort, disease stabilization was observed in two of the five patients treated, with one patient achieving red blood cell transfusion independence. In the second cohort, disease stabilization was observed in two of the four patients treated. In the third cohort, disease stabilization was observed in all four of the patients treated, with a reduction in bone marrow

blasts observed in two of the four patients and the clearance of peripheral blasts observed in one patient. Two patients achieved more than 50 percent bone marrow blast reduction, with one of these patients observing an increase in platelet count without transfusions. The fourth cohort, evaluating a weekly regimen of LYT-200 at the 12 mg/kg dose, is still ongoing. The part 2 portion of the Phase 1b trial evaluating LYT-200 in combination with venetoclax and hypomethylating agents is also ongoing. PureTech plans to present additional data from the trial in a scientific forum in 2024.

#### **Founded Entities:**

#### Karuna Therapeutics (Nasdag: KRTX) (Karuna)

- Announced the U.S. Food and Drug Administration has accepted its New Drug Application (NDA) for KarXT (xanomeline-trospium) for the treatment of schizophrenia in adults. The application has been granted a Prescription Drug User Fee Act (PDUFA) date of September 26, 2024.
- Announced positive results from its Phase 1b open-label, eight-week inpatient trial evaluating the
  effect of KarXT on 24-hour ambulatory blood pressure in adults with schizophrenia demonstrating
  that KarXT was not associated with increases in blood pressure.
- The transaction of Karuna shares as described in this paragraph constitutes a class 2 transaction for the purposes of the UK Financial Conduct Authority's Listing Rules. Since October 12, 2023, PureTech has raised aggregate proceeds of approximately \$31.9 million, net of transaction fees, through the sale of shares of Karuna in on-market transactions and the completion of call options (collectively, the "Transaction"). PureTech also notes that it may, but is not committing to, undertake sales of Karuna shares to generate additional proceeds consistent with prior transactions at its discretion. The proceeds of the Transaction are held by PureTech as Cash and Cash Equivalents, and PureTech intends to use the proceeds from the Transaction to further the advancement and growth of the Company. Following the Transaction, PureTech holds 892,852 shares of Karuna common stock, which is equal to approximately 2.4 percent of Karuna's outstanding shares as of October 31, 2023, with a market value of approximately \$195.6 million as of December 19, 2023. Any future changes in our holdings will be reflected through standard updates of our corporate presentation and our other reporting. PureTech is also eligible to receive up to \$400 million in potential future milestone payments from its deal with Royalty Pharma and retains the right to certain royalty payments based on the sales of KarXT, as well as 20 percent sublicense income covered by PureTech's license agreement with Karuna.

#### Vedanta

- Dosed the first patient in the Phase 2 COLLECTIVE202 clinical study of VE202 for the treatment of ulcerative colitis. The FDA also granted Fast Track designation to VE202.
- Expects to initiate the Phase 3 RestoratiVE303 pivotal study of VE303, designed for the prevention of recurrent Clostridioides difficile infection, in the coming months.

## Vor (Nasdaq: VOR)

o Presented updated clinical data from patients treated in VBP101, its Phase 1/2a multicenter, open-label, first-in-human study of trem-cel (VOR33) in patients with acute myeloid leukemia (AML) at the ASTCT/EBMT 6<sup>th</sup> International Conference on Relapse After Transplant and Cellular Therapy (HSCT²). The additional data demonstrated successful engraftment of trem-cel in all seven patients treated to date with trem-cel. All three patients treated with Mylotarg experienced hematologic protection and CD33-negative donor cell enrichment with multiple cycles.

## o Entrega

- Advanced its platform for the oral administration of biologics, vaccines and other drugs that are otherwise not efficiently absorbed when taken orally. Entrega's technology platform uses a proprietary, customizable hydrogel dosage form to control local fluid microenvironments in the GI tract to both enhance absorption and reduce the variability of drug exposure. Peptide therapeutics (e.g., the emerging GLP-1 agonist class) are ideally suited to benefit from Entrega's approach.
- Demonstrated increased oral peptide bioavailability of two- to three-fold over standard permeation enhancer formulations.

#### o Akili, Inc. (Nasdaq: AKLI) (Akili)

- o Announced it received authorization from the U.S. FDA to expand the label for EndeavorRx<sup>®7</sup> from 8 to 12 year-old patients with primarily inattentive or combined-type attention-deficit/hyperactivity disorder (ADHD) who have a demonstrated attention issue to include older children aged 13-17. This increased age range is expected to more than double the number of pediatric patients with ADHD who are now eligible for EndeavorRx.
- Announced its strategic plan to transition from a prescription to a non-prescription business model.
   Akili also submitted a 510(k) application to the FDA for EndeavorOTC<sup>8</sup> as an over-the-counter treatment for adults with ADHD.
- Announced it plans to submit data to the FDA to convert its pediatric prescription product, EndeavorRx, to OTC in 2024.
- O Announced topline results of the STARS-ADHD-Adult clinical trial evaluating the efficacy and safety of EndeavorRx (AKL-T01) in adults with ADHD. The results demonstrated attention improved in more than 80 percent of adults with ADHD, and over one-third of participants no longer exhibited an attention deficit following treatment. Improvements in attention were nearly seven times larger than those seen in the pivotal trial that supported EndeavorRx's FDA authorization for 8 to 12 year-olds with ADHD. Additionally, nearly half of adults treated with EndeavorRx met a prespecified threshold for clinically meaningful improvement in their quality of life. EndeavorRx treatment was well-tolerated, with minimal side effects and no serious device-related adverse events reported.

#### o Sonde Health

Continued to scale its sales and revenue growth through partnerships with several top health companies, providers, pharma and device original equipment manufacturers. Sonde's voice-based artificial intelligence platform has now generated over 1.2 million voice samples from more than 85,000 individuals on four continents.

As part of PureTech's distinctive approach to drug development, which includes efficient de-risking and deprioritizing of programs that don't reach pre-specific thresholds for advancement, the Company is no longer advancing its Alivio™ platform, including therapeutic candidates LYT-500 and LYT-510, to pivot resources towards the programs with the highest probability of success. Additionally, PureTech announced in October that it would not be moving forward with the previously contemplated plan of merger with Gelesis.

#### **About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep pipeline through its experienced research and development team and its extensive network of scientists, clinicians and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 28 therapeutics and therapeutic candidates, including two (Plenity® and EndeavorRx®) that have received both US FDA clearance and European marketing authorization and a third (KarXT) that has been filed for FDA approval. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration enabling studies. All of the underlying programs and platforms that resulted in this pipeline of therapeutic candidates were initially identified or discovered and then advanced by the PureTech team through key validation points.

For more information, visit www.puretechhealth.com or connect with us on X (formerly Twitter) @puretechh.

#### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains statements that are or may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation those related to the Company's LYT-100 development program and the timing for results from ongoing clinical trials of LYT-100, the LYT-200 development program and the timing for results from ongoing clinical trials of LYT-200, the planned initiation of clinical trials for LYT-300, LYT-310 and LYT-320, the potential therapeutic benefits of the therapeutic candidates

within Company's Wholly Owned Programs, the Company's plan related to the prioritization of programs and activities associated with its pipeline, the Company's approach to potential partnerships or spinouts of its platforms or candidates, the Company's plans to maintain a minimum of three years of cash on hand, the Company's plans to return capital to shareholders and its future prospects, developments and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks, uncertainties and other important factors that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to the following: our history of incurring significant operating losses since our inception; our need for additional funding to achieve our business goals, which may not be available and which may force us to delay, limit or terminate certain of our therapeutic development efforts; our limited information about and limited control or influence over our Founded Entities; the generally lengthy and expensive process of preclinical and clinical drug development, which has an uncertain outcome and potential for substantial delays; potential difficulties with enrolling patients in clinical trials, which could delay our clinical development activities; side effects, adverse events or other safety risks which could be associated with our therapeutic candidates and delay or halt their clinical development; our ability to obtain regulatory approval for and commercialize our therapeutic candidates; our ability to realize the benefits of our collaborations, licenses and other arrangements; our ability to maintain and protect our intellectual property rights; our reliance on third parties, including clinical research organizations, clinical investigators and manufacturers; our vulnerability to natural disasters, global economic factors, geo-political actions and unexpected events; our ability to achieve future monetization events; limitations on our ability to pay cash to shareholders; those risks, uncertainties and other important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2022 filed with the SEC and in our other regulatory filings. These forward-looking statements are based on assumptions regarding the present and future business strategies of the Company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, we disclaim any obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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The preliminary selected financial results reported by the Company are unaudited, subject to adjustment, and provided as an  $^{[1]}$ 

approximation in advance of the Company's announcement of complete financial results in April 2024.

- <sup>2</sup>References to "Wholly Owned Programs" refer to the Company's five therapeutic candidates (LYT-100, LYT-200, LYT-300, LYT-310 and LYT-320), Glyph platform and potential future therapeutic candidates and platforms that the Company may develop or obtain. References to "Wholly Owned Pipeline" refer to LYT-100, LYT-200, LYT-300, LYT-310 and LYT-320. Certain of the Wholly Owned Programs and certain assets within the Wholly Owned Pipeline are being advanced through the newly announced Founded Entities Seaport Therapeutics, Inc. and Gallop Oncology, Inc.
- <sup>3</sup> Founded Entities represent companies founded by PureTech in which PureTech maintains ownership of an equity interest and, in certain cases, is eligible to receive sublicense income and royalties on product sales. As of the date of this release, PureTech maintained control over Entrega, Inc. by virtue of majority voting control and the right to elect representation to the entity's Board of Directors. PureTech also controls Seaport Therapeutics, Inc. and Gallop Oncology, Inc. As of the date of this release, PureTech did not have a controlling interest in Karuna Therapeutics, Inc., Akili, Inc., Sonde Health, Inc., Vedanta Biosciences, Inc. and Vor Biopharma Inc.
- <sup>4</sup> The percentage includes number of successful trials out of all trials run for all therapeutic candidates advanced through at least Phase 1 by PureTech or its Founded Entities from 2009 onward.
- <sup>5</sup> Industry average data measures the probability of clinical trial success of therapeutics by calculating the number of programs progressing to the next phase vs. the number progressing and suspended (Phase 1=52%, Phase 2=29%, Phase 3=58%). BIO, PharmaIntelligence, QLS (2021) Clinical Development Success Rates 2011 -2020. This study did not include therapeutics regulated as devices.
- <sup>6</sup> Any Anxiety Disorder. (n.d.). National Institute of Mental Health (NIMH). https://www.nimh.nih.gov/health/statistics/any-anxiety-disorder
- TendeavorRx is the first-and-only FDA-authorized treatment delivered through a video game experience. EndeavorRx is indicated to improve attention function as measured by computer-based testing in children ages 8 to 12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorRx demonstrate improvements in a digitally assessed measure Test of Variables of Attention (TOVA®) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder. EndeavorRx is available by prescription only. It is not intended to be used as a stand-alone therapeutic and is not a substitution for a child's medication. The most common side effect observed in children in EndeavorRx's clinical trials was a feeling of frustration, as the game can be quite challenging at times. No serious adverse events were associated with its use. EndeavorRx is recommended to be used for approximately 25 minutes a day, 5 days a week, over initially at least 4 consecutive weeks, or as recommended by your child's health care provider. To learn more about EndeavorRx, please visit EndeavorRx.com.
- <sup>8</sup> EndeavorOTC is a digital therapeutic indicated to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD. EndeavorOTC utilizes the same proprietary technology underlying EndeavorRx, a prescription digital therapeutic indicated to improve attention function in children ages 8-12. EndeavorOTC is available under the U.S. Food and Drug Administration's current Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. EndeavorOTC has not been cleared or authorized by the U.S. Food and Drug Administration for its indications. It is recommended that patients speak to their health care provider before starting EndeavorOTC treatment. No serious adverse events have been reported in any of our clinical studies. To learn more, visit EndeavorOTC.com.

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