PureTech Founded Entity Follica Announces Positive Feedback from FDA as it Prepares to Advance its Lead Programme in Male Androgenetic Alopecia into Phase 3 Development

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Follica plans to initiate its Phase 3 programme this year

PureTech Health plc (LSE: PRTC) ("PureTech"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, is pleased to note that its Founded Entity, Follica, today announced positive feedback from an End of Phase 2 meeting with the US Food and Drug Administration (FDA) for its lead programme to treat male androgenetic alopecia. The company plans to advance the programme into Phase 3 development this year following the successful safety and efficacy optimisation study announced in December 2019.

Bharatt Chowrira, JD, PhD, president and chief of business and strategy at PureTech, said: "This positive feedback from FDA enables Follica to move forward with its pivotal trial this year. Current treatments for the progressive hair loss caused by androgenetic alopecia are inadequate, and we are pleased with Follica's progress towards Phase 3 development, bringing us another step closer to a potential new treatment for the millions of people seeking safe, effective, non-surgical treatments to grow new hair."

The full text of the announcement from Follica is as follows:

Follica Announces Positive Feedback from End of Phase 2 Meeting with FDA for its Lead Programme to Treat Male Androgenetic Alopecia

Company plans to initiate its Phase 3 programme this year

BOSTON, June 4, 2020 -- Follica, Inc. ("Follica"), a biotechnology company developing a regenerative platform designed to treat androgenetic alopecia, epithelial ageing and other related conditions, today announced positive feedback from a meeting with the US Food and Drug Administration (FDA) as the company prepares to advance its lead programme into Phase 3 development following a successful safety and efficacy optimisation study for the treatment of hair loss in male androgenetic alopecia announced in December 2019.

Follica plans to launch its Phase 3 this year. Overall, approximately 280 patients will be enroled, with efficacy assessed against two co-primary endpoints: visible (non-vellus) hair count and patient-reported outcomes on a pre-established scale. The randomised, controlled, double-blinded studies will be conducted in multiple centers across the US. A maximal use study to further understand the pharmacokinetics of the treatment will be conducted in parallel. The trial design is consistent with feedback from the FDA during the End of Phase 2 meeting.

"In the US alone, 47 million men are affected by progressive hair loss caused by androgenetic alopecia, a condition that is largely unresolved today, leaving many dissatisfied with the current available treatments and looking for a new alternative. Our recent safety and optimisation study points to a new level of effect, enabled by our proprietary approach, which stimulates the growth of new follicles and new hair," said Jason Bhardwaj, chief executive officer of Follica. "We're grateful to the FDA for their guidance as we prepare for our pivotal programme, and we look forward to advancing the development of our treatment regimen, which has demonstrated strong potential to address the current need for those who seek treatment for androgenetic alopecia."

Follica's approach is based on generating an "embryonic window" in adult scalp cells via a series of short office-based treatments with its proprietary Hair Follicle Neogenesis (HFN) device. The scalp treatments, which last just a few minutes, stimulate stem cells and enable the growth of new hair follicles. A topical drug is then applied to enhance efficacy by growing and thickening new hair follicles and hair on the scalp.

Follica reported topline results from its safety and optimisation study in December 2019. That trial was designed to select the optimal treatment regimen using Follica's proprietary HFN device in combination with a topical drug and successfully met its primary endpoint. The selected treatment regimen demonstrated a statistically significant 44% improvement of visible (non-vellus) hair count after three months of treatment compared to baseline ($p < 0.001$, $n = 19$). Across all three treatment arms, the overall improvement of visible (non-vellus) hair count after three months of treatment was 29% compared to baseline ($p < 0.001$, $n = 48$), reflecting a clinical benefit across the entire trial population and a substantially improved outcome with the optimal treatment regimen. Additionally, a prespecified analysis comparing the 44% change in visible (non-vellus) hair count to a 12% historical benchmark set by approved pharmaceutical products established statistical significance ($p = 0.005$).

In addition to the safety and optimisation study, Follica has validated its approach in prior clinical studies using prototype HFN devices with different treatment parameters and therapeutic compounds. Follica's translational work builds on research by George Cotsarelis, MD, who isolated and characterised the expression pattern of stem cells from a critical region of the follicle. An expert in epithelial stem cell biology, Dr Cotsarelis is chair of the department of dermatology at the University of Pennsylvania and a co-founder of Follica.

About Androgenetic Alopecia

Androgenetic alopecia represents the most common form of hair loss in men and women, with an estimated 90 million people who are eligible for treatment in the United States alone. Only two drugs, both of which have demonstrated a 12% increase of non-vellus hair count over baseline for their primary endpoints, are currently approved for the treatment of androgenetic alopecia[1]. The most effective current approach for the treatment of hair loss is hair transplant surgery, comprising a range of invasive, expensive procedures for a subset of patients who have enough donor hair to be eligible. As a result, there remains a significant need for safe, effective, non-surgical treatments to grow new hair.

About Follica

Follica is a biotechnology company developing a regenerative platform designed to treat androgenetic alopecia, epithelial ageing and other related

conditions. Founded by PureTech (LSE: PRTC), a co-inventor of the current platform, and a group of world-renowned experts in hair follicle biology and regenerative medicine, Follica's experimental treatment platform has been shown to stimulate the development of new hair follicles and hair in three previously conducted clinical studies. The company's proprietary treatment is designed to induce an embryonic window via a device with optimised parameters to initiate hair follicle neogenesis, the formation of new hair follicles from epithelial (skin) stem cells. This process is enhanced through the application of a topical compound. Follica completed a safety and efficacy optimisation study in 2019, and its Phase 3 programme in male androgenetic alopecia is expected to begin in 2020. Follica's technology is based on work originating from the University of Pennsylvania that has been further developed by Follica's internal programme. Follica's extensive IP portfolio includes IP exclusively licensed from the University of Pennsylvania as well as Follica-owned IP.

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, including intractable cancers, lymphatic and gastrointestinal diseases, central nervous system disorders and inflammatory and immunological diseases, among others. The Company has created a broad and deep pipeline through the expertise of its experienced research and development team and its extensive network of scientists, clinicians and industry leaders. This pipeline, which is being advanced both internally and through PureTech's Founded Entities, is comprised of 23 product candidates and one product that has been cleared by the US Food and Drug Administration (FDA). All of the underlying programmes and platforms that resulted in this pipeline of product candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on the Company's unique insights into the biology of the brain, immune and gut, or BIG, systems and the interface between those systems, referred to as the BIG Axis.

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

Forward Looking Statement

This press release contains statements that are or may be forward-looking statements, including statements that relate to the company's future prospects, developments, and strategies. The forward looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks and uncertainties described in the risk factors included in the regulatory filings for PureTech Health plc. 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, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

[1] Olsen EA et al, *J Am Acad Dermatol*. 2002 Sep;47(3):377-85

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Price VH et al, *J Am Acad Dermatol.* 2002 Apr;46(4):517-23

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