



Follica Announces Positive Interim Data and Progression to Pivotal Study in Male Androgenetic Alopecia

June 13, 2019

Pivotal study expected to begin in late 2019

PureTech Health has increased its ownership in Follica to 77%

[PureTech Health](#) plc (LSE: PRTC) ("PureTech Health"), an advanced biopharmaceutical company developing novel medicines for dysfunctions of the Brain-Immune-Gut (BIG) axis, is pleased to note that its affiliate, Follica, announced today that it will progress the program to a pivotal study following positive interim data from an ongoing safety and optimisation study in male androgenetic alopecia (male pattern hair loss). In addition to demonstrating tolerability and informing key treatment parameters, the study achieved a visible and statistically significant improvement in non-vellus (visible) hair count after three months of treatment, compared to baseline, according to an analysis of 20 study participants. Additionally, blinded head-to-head bench testing of the proprietary Follica device has shown significant therapeutic advantages in scalp treatment versus commercially available skin disruption devices. A pivotal study is expected to initiate at the end of 2019 subject to continued safety and efficacy in the optimisation study. PureTech Health has increased its ownership in Follica and now holds a 77%ⁱ equity stake in the company, in addition to royalties from potential sales.

Daphne Zohar, founder and chief executive officer of PureTech Health, said: "Follica is an affiliate that we haven't spoken about as much pending these results, so we are excited to share this positive development as the company prepares to initiate its pivotal study toward the end of this year. The interim analysis showed a robust response to Follica's proprietary treatment and we believe the company is uniquely positioned to potentially address a tremendous need in a large market."

Follica's platform is designed to induce an "embryonic window" in adult skin via a proprietary form of micro-abrasion that initiates hair follicle neogenesis, the formation of new hair follicles from epithelial (skin) stem cells. This process of hair follicle neogenesis is enhanced through the application of a topical compound as part of the treatment regimen. In addition to the ongoing safety and optimisation study, Follica has proof-of-concept data from prior clinical studies using prototype devices with different treatment parameters and therapeutic compounds.

ⁱ Calculated on a diluted basis, including issued and outstanding shares as well as outstanding options to purchase shares, excluding unallocated shares authorised to be issued pursuant to equity incentive plans, and assuming conversion of outstanding promissory notes.

The full text announcement from Follica is as follows:

Follica Announces Progression to Pivotal Study Following Positive Interim Data in Male Androgenetic Alopecia

Pivotal study expected to begin in late 2019

BOSTON, June 13, 2019 —[Follica, Inc.](#) ("Follica"), a clinical-stage biotech developing a regenerative platform for hair growth, today announced positive interim data from an ongoing safety and optimisation study to treat hair loss in male androgenetic alopecia. In addition to being well tolerated and informing key treatment parameters, analysis of 20 male study participants with androgenetic alopecia showed that Follica's approach achieved a visible and statistically significant improvement in non-vellus (visible) hair count after three months of treatment, compared to baseline. Additionally, blinded head-to-head bench testing of the proprietary Follica device has shown significant therapeutic advantages in scalp treatment versus commercially available skin disruption devices. A pivotal study is expected to initiate at the end of 2019 subject to continued safety and efficacy in the optimisation study.

Follica's platform is designed to induce an "embryonic window" in adult skin via a proprietary form of micro-abrasion that initiates hair follicle neogenesis, the formation of new hair follicles from epithelial (skin) stem cells. This process of hair follicle neogenesis is enhanced through the application of a topical compound as part of the treatment regimen. In addition to the ongoing safety and optimisation study, Follica has proof-of-concept data from prior clinical studies using prototype devices with different treatment parameters and therapeutic compounds. Follica's translational work builds on an important basic discovery by George Cotsarelis, MD, Chair of the Department of Dermatology at the University of Pennsylvania, and a co-founder of Follica.

"Follica's pioneering work in new hair formation has the potential to address a tremendous need," said Ken Washenik, MD, PhD, president of Bosley Medical Group, clinical faculty of Dermatology at NYU school of medicine, and senior medical advisor to Follica. "The unique mechanism of action has been studied extensively and is truly differentiated from existing treatment options. The results I've reviewed in the interim analysis are exciting and very strong, and I look forward to the initiation of the pivotal study later this year."

"Some of my past life was spent trying to stop hair from growing, but I'm equally enthusiastic to have been involved in helping advance and optimise George's key discovery that shows promise for creating new hair," said R. Rox Anderson, MD, PhD, professor of dermatology at Harvard Medical School, director of the Massachusetts General Hospital Laser Center, and scientific advisor to Follica, who conceived and developed many of the non-scarring treatments now widely used in medical and aesthetic care. These include laser treatments for birthmarks, microvascular and pigmented lesions, tattoo and permanent hair removal, as well as cryolipolysis (Coolsculpting®).

"The biology of wounding in humans is very complex, and our ability to translate its effects into new hair growth is sensitive to a range of treatment

factors,” said Jason Bhardwaj, chief executive officer of Follica. “From years of clinical testing, we have optimised the dosing, frequency, and several other important parameters and translated these learnings into a unique and proprietary treatment. Based on this interim analysis and the results of three previously conducted studies, we are excited to move forward into a pivotal study at the end of 2019.”

The safety and optimisation study is an endpoint-blinded, randomised, controlled study designed to evaluate Follica’s proprietary skin disruption device in men with androgenetic alopecia and to establish therapeutic parameters, including the optimal duration and frequency of treatment. The study will continue to enrol up to 60 men, ages 18-40, with moderate grades of androgenetic alopecia (Hamilton Norwood III-IV).

About Follica

Follica is a clinical-stage biotech developing a regenerative platform for hair growth. Founded by PureTech Health (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 device platform has been shown to stimulate the development of new hair follicles and hair in three previously conducted clinical studies. The company’s proprietary device is designed to induce an embryonic window via a device with optimised parameters to create micro-abrasions and 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 is conducting an ongoing optimisation trial, with a pivotal study in androgenetic alopecia expected to begin at the end of Q4 2019. Follica’s technology and strong IP is based on work exclusively licensed from the University of Pennsylvania that has been further enhanced and protected by Follica’s internal development work.

About PureTech Health

PureTech Health (LSE: PRTC) is an advanced biopharmaceutical company developing BIG medicines for dysfunctions of the Brain-Immune-Gut axis. The Company has gained deep insights into the connection between these systems and the resulting role in diseases that have proven resistant to established therapeutic approaches. By harnessing this emerging field of human biology, PureTech Health is developing new categories of medicines with the potential to have great impact on people with serious diseases.

PureTech Health is advancing a rich pipeline of innovative therapies with an unbiased, non-binary, and capital efficient R&D model across its affiliates and its internal labs. PureTech’s affiliates include seven clinical-stage platforms, including one product that has been cleared by the US Food and Drug Administration (FDA) and a second product candidate that has been filed with the FDA for review, and several other novel preclinical programmes. The PureTech Health pipeline includes ground-breaking platforms and therapeutic candidates that were developed in collaboration with some of the world’s leading experts.

PureTech’s internal research and development is centred on tissue-selective immunomodulation for the treatment of oncology, autoimmune, and CNS-related disorders, with a near-term focus on targeting newly-discovered, foundational immunosuppressive mechanisms in oncology and novel approaches that harness the lymphatic infrastructure.

For more information, visit www.puretechhealth.com or connect with us on Twitter [@puretechh](https://twitter.com/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.