



PureTech's Alivio Awarded \$3.3 Million Grant from the US Department of Defense to Advance Product Candidate for the Treatment of Interstitial Cystitis/Bladder Pain Syndrome

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Award to advance product candidate towards potential investigational new drug filing

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 Alivio Therapeutics, Inc., an affiliate of PureTech Health, today announced a \$3.3 million US Department of Defense (DoD) Technology/Therapeutic Development Award. The funds will support Alivio's preclinical research and development activities for product candidate, ALV-107, which is being advanced for the treatment of interstitial cystitis/bladder pain syndrome (IC/BPS) with Hunner's lesions.

Joseph Bolen, PhD, Chief Scientific Officer at PureTech Health, said: "Existing therapies for inflammatory diseases are often limited by side effects or a lack of clinically meaningful efficacy primarily due to a narrow therapeutic window. This grant provides further validation of the substantial opportunity to advance Alivio's inflammation-targeting technology as a new approach to address inflammatory diseases at the sites of inflammation and to potentially provide a new therapeutic option for diseases, such as interstitial cystitis, where there is a major unmet need."

The full text announcement from Alivio is as follows:

US Department of Defense Awards \$3.3 Million Grant to Alivio Therapeutics

Research award will support preclinical activities to advance product candidate for the treatment of interstitial cystitis/bladder pain syndrome into the clinic

BOSTON, September 12, 2018 — [Alivio Therapeutics](#), an affiliate of [PureTech Health plc](#) (LSE: PRTC) developing therapies to treat inflammatory disorders through targeted disease immunomodulation, today announced a \$3.3 million US Department of Defense (DoD) Technology/Therapeutic Development Award to advance Alivio's product candidate, ALV-107, for the treatment of interstitial cystitis/bladder pain syndrome (IC/BPS) with Hunner's lesions. The funds will support Alivio's preclinical research and development activities, including GMP manufacturing, to enable the filing of an investigational new drug (IND) application for ALV-107.

Alivio's inflammation-targeting technology is designed to administer therapeutics to the sites of inflammation, while sparing healthy tissue. The technology is also engineered to respond dynamically to inflammation, releasing the entrapped therapeutics based on the degree of inflammation present. This approach is being evaluated across a variety of diseases, including IC/BPS, pouchitis, and inflammatory bowel disease (IBD).

J Curtis Nickel, MD FRCS, Professor, CIHR Canada Research Chair in Urologic Pain and Inflammation at Queen's University, said: "Interstitial cystitis is one of the most important unmet needs in urology. New therapies that can offer long-lasting relief from the pain associated with the disease would make a major impact in the lives of patients. I am hopeful that this award will accelerate development of this potentially new therapy for interstitial cystitis/bladder pain syndrome and look forward to seeing ALV-107's impact in the clinic."

"Our inflammation-targeting technology approach has the potential to treat a range of chronic and acute inflammatory disorders, such as interstitial cystitis/bladder pain syndrome with Hunner's lesions, that would otherwise be difficult to treat," said Eric Elenko, PhD, PureTech's Chief of Strategy and Research and Alivio Co-founder. "ALV-107 could potentially offer a novel therapeutic option to improve the health of patients living with this devastating disease, and this award will help to support our effort to advance ALV-107 towards the clinic."

Alivio's platform technology has demonstrated proof-of-concept in ten different preclinical models of inflammation including a validated preclinical model for the treatment of IC/BPS. ALV-107 showed durable pain control throughout a 24-hour study period in this model of IC/BPS, lasting at least 12 times longer than lidocaine at a comparable dose (ALV-107 16 mg/kg, conventional lidocaine 16 mg/kg). Beyond ALV-107, Alivio is advancing additional product candidates to enable new immunomodulatory therapies and active pharmaceutical ingredients (APIs), including biologics, and nucleic acids for inflammatory conditions of the GI tract and other parts of the body.

About Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS) and Hunner's Lesions

Interstitial Cystitis or Bladder Pain Syndrome (IC/BPS) is a chronic bladder condition that consists of discomfort or pain in the bladder or surrounding pelvic region and is often associated with frequent urination. It is estimated to affect up to 12 million people in the US and is more common in women than men. Current treatments fail to control pain in many patients, particularly patients with Hunner's lesions, which are estimated to affect 5-10% of IC/BPS patients in the US.

About the US Department of Defense Award

The US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. This work is supported by the Office of the Assistant Secretary of Defense through the Peer Reviewed Medical Research Program under Award No. W81XWH-18-1-0566. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

About Alivio

Alivio Therapeutics, Inc., an affiliate of PureTech Health (PRTC.L), is pioneering targeted disease immunomodulation as a novel strategy to treat a range of chronic and acute inflammatory disorders. Targeted disease immunomodulation involves tuning the immune system exclusively at the site of disease in the body, with minimal impact on the rest of the immune system. This long sought-after approach has potential to treat a range of chronic and acute inflammatory disorders including ones that would otherwise be difficult to treat. Based on the research of Dr Karp and Dr Robert Langer, David H Koch Institute Professor at MIT, Alivio's proprietary inflammation-targeting platform is designed to administer therapeutics to the sites of inflammation, while sparing healthy tissue. The technology is also engineered to respond dynamically to inflammation, releasing the entrapped therapeutics based on the degree of inflammation present. Alivio's pipeline includes candidates for interstitial cystitis/bladder pain syndrome (IC/BPS), pouchitis, and inflammatory bowel disease (IBD).

The technology platform has been published in peer-reviewed journals, including in [Science Translational Medicine](#) and [Nature Communications](#), and the technology is the first of its kind to demonstrate reproducible targeting of immunomodulatory compounds to inflamed tissue in preclinical models, having been validated in multiple labs and in ten different preclinical models of inflammation where the inflammation occurred in different parts of the body (e.g., the GI system, the bladder, joints, skin, etc.). The technology could potentially be used with a variety of medications (e.g., small molecules, biologics, and nucleic acids) both independently or in combination and is designed to be administered orally or via other routes. With this platform, Alivio aims to address the dozens of conditions where inflammation is a central part of the underlying disease pathology, but where targeted and effective treatment options are lacking.

Alivio is developing its therapies in collaboration with several of the world's leading experts in biomaterials and immunology. Expert advisors include: [Jeffrey Karp, PhD](#), Professor of Medicine at Brigham and Women's Hospital and Alivio co-founder; [Robert Langer, ScD](#), Alivio co-founder and Non-Executive Director at PureTech Health and David H Koch Institute Professor at MIT; Michael B Brenner, MD, Chief of the Division of Rheumatology, Immunology and Allergy at BWH; [Ulrich H von Andrian, MD, PhD](#), Mallinckrodt Professor of Immunopathology at Harvard Medical School; and [Ralph Weissleder, MD, PhD](#), Director of the Center for Systems Biology at Massachusetts General Hospital.

About PureTech Health

PureTech Health (LSE: PRTC) is an advanced biopharmaceutical company developing novel medicines for dysfunctions of the Brain-Immune-Gut (BIG) Axis. The Company has developed deep insights into the connection between the individual components of these systems and the resulting role in many chronic diseases, which 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 across two divisions: the Affiliates division and the Internal division. Its Affiliates division includes two product candidates that have been filed with the US Food and Drug Administration (FDA) for review and several other novel clinical and pre-clinical programmes. These affiliates are developing ground-breaking platforms and therapeutic candidates in collaboration with some of the world's leading experts.

PureTech's Internal division is advancing a pipeline fuelled by recent discoveries in lymphatics and immune cell trafficking to modulate disease in a tissue-specific manner. These programmes leverage the transport and biodistribution of various immune system components for the targeted treatment of diseases with major unmet needs, including cancers, autoimmune diseases, and neuroimmune disorders.

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.