

## NEWS RELEASE

### **PORTAGE 'S BIOHAVEN RECEIVES RESPONSE FROM FDA TO ITS PRE-IND MEETING REQUEST**

*Biohaven filed a pre-IND meeting request with the FDA regarding lead investigational agent BHV-0223, receives written response in lieu of an in-person meeting*

**Toronto, Ontario, December 18, 2014** – Portage Biotech Inc. (“Portage”) (OTCQB: PTGEF, Canadian Stock Exchange: PBT.U), is pleased to announce that Biohaven Pharmaceutical Holding Company Limited (Biohaven), where in Portage holds 54% equity, received a written response from Food and Drug Administration (FDA) regarding its Pre-Investigational New Drug Application (PIND) meeting request and accompanying briefing book materials submitted to the agency in regard to BHV-0223. The FDA communicated that a written response was being issued in lieu of an in person meeting. The correspondence from the agency indicated that the proposed doses of BHV-0223 appeared reasonable. No issues were identified in the correspondence that would pose a barrier to Biohaven’s planned filing of an investigational new drug application (IND) for BHV-0223.

Declan Doogan M.D., CEO of Portage and Executive Chairman of BioHaven, commented, “Overall, the written response received from the FDA was in-line with our expectations and no issues were raised that would prevent the timely filing of our IND or initiation of our first Phase 1 study. This is very good news for Biohaven and reflects the team's expertise in the submission of high quality regulatory documents.”

“With this feedback from the FDA, Biohaven has already initiated the work streams necessary to file our IND for BHV-0223. We are excited about completing the optimization of our commercial formulation of BHV-0223, submitting the IND and initiating clinical studies in 2015,” commented Robert Berman M.D. Chief Medical Officer of Biohaven and Adjunct Professor of Psychiatry, Yale University School of Medicine.

BHV-0223 is a reformulated glutamate modulating agent being developed for treatment-resistant mood and general anxiety disorders. (GAD)

GAD affects approximately 6.8 million adults or 3% of the U.S. population. GAD is often a chronic disorder with significant impairment in social and work functioning. GAD is characterized by excessive anxiety and uncontrollable worry that interferes with an individual’s daily functioning. Anxiety symptoms are often accompanied by restlessness, fatigue, difficulty concentrating, irritability, muscle tension and increased sleep. GAD is more common in women

than men and is often characterized by a chronic course. Current medication treatments are fully effective in only half of patients and improved treatments are needed.

***About Portage:***

Portage is engaged in researching and developing pharmaceutical and biotech products through to clinical “proof of concept” with an initial focus on unmet clinical needs. Following proof of concept, Portage will look to sell or license the products to large pharmaceutical companies for further development and commercialization.

Portage is seeking discovery and co-development partners in areas such as certain inherited diseases, inflammatory and autoimmune disease, cancer, infectious disease, neurology and psychiatry developing novel targeted therapies, and even older marketed products that have been found to have novel patentable characteristics that bring new value to patients

Portage seeks to work with a wide range of partners, in all phases of development through in-licensing or other types of alliances. The collaboration may include direct funding or investing human capital from our extensive pool of talented scientists and physicians. Specifically Portage will invest sweat equity as well as, or instead of, capital. This internal pool of drug developers, financiers, scientists and physicians will provide unique value-add for our partners including but not limited to mitigating risks, clinical trial design, regulatory expertise and maximizing the rewards.

Apart from Biohaven, Portage also has fully owned subsidiary, Portage Pharmaceuticals Limited (PPL). PPL has successfully validated a new proprietary cell permeable peptide platform technology derived from human genes. This proprietary platform technology has been shown to efficiently deliver an active pharmacological agent or cargo into a cell without disrupting the cell membrane. The platform has favorable pharmaceutical properties simplifying formulation development for systemic and locally administered conjugates which will allow more rapid development of drug products. PPL has converted its previously filed provisional patent application for this delivery system to an international patent application that includes a variety of structures utilizing cargos that address important areas of medical need.

PPL has prioritized inflammation as an area with a large therapeutic opportunity. Using a cargo peptide against an anti-inflammatory target, PPL has demonstrated not only cell penetration but also convincing in-vitro and in-vivo pharmacological effects mediated intracellularly. PPL has further validated its platform cell penetrating peptide technology for safely delivering a potent anti-inflammatory cargo into eye tissues. Its lead compound PPL-003 showed success in two studies in rabbits. In the first study, topical eye administration of PPL-003 at the highest feasible dose was well tolerated with no abnormal clinical or pathological findings. In the second study PPL-003 demonstrated efficacy in an experimental uveitis model by significantly suppressing the cellular inflammatory response in the anterior chamber and reducing the protein content of the anterior chamber aqueous humor. These results in rabbits clearly demonstrated at least a ten-fold safety margin and confirmed the topical anti-inflammatory activity of PPL-003 previously demonstrated in a mouse uveitis model. PPL is continuing its uveitis program working toward an IND submission in 2016.

For further information, contact Dr. Greg Bailey, the Chairman at [gb@portagebiotech.com](mailto:gb@portagebiotech.com) or Kam Shah, Chief Financial Officer, at (416) 929-1806 or [ks@portagebiotech.com](mailto:ks@portagebiotech.com) or visit our website at [www.portagebiotech.com](http://www.portagebiotech.com).

### Forward-Looking Statements

This news release includes forward-looking statements within the meaning of the U.S. federal and Canadian securities laws. Any such statements reflect Portage's current views and assumptions about future events and financial performance. Portage cannot assure that future events or performance will occur. Important risks and factors that could cause actual results or events to differ materially from those indicated in our forward-looking statements.

Portage assumes no obligation and expressly disclaims any duty to update the information in this News Release.