

## NEWS RELEASE

### **PORTAGE'S BIOHAVEN ANNOUNCES EXPEDITED DEVELOPMENT PATH FOR BHV-0223 FOLLOWING SUCCESSFUL PRE-IND INTERACTION WITH FDA**

#### **Biohaven Plans for Timely Completion of Bioequivalence Study and NDA Submission**

**Toronto, Ontario, February 25, 2016** – Portage Biotech Inc. (“Portage”) (OTC Market: PTGEF, Canadian Securities Exchange: PBT.U), and Biohaven Pharmaceutical Holding Company Limited (Biohaven), announced receiving favorable and productive feedback from their Pre-Investigational New Drug Application (PIND) interaction with the Food and Drug Administration (“FDA”). Biohaven received a written response from FDA in lieu of an in-person meeting. The PIND response pertained to Biohaven’s investigative product, BHV-0223, and the intended initial registrational program for the indication of amyotrophic lateral sclerosis (“ALS”).

BHV-0223 is a unique formulation of riluzole, a glutamate modulating agent, that utilizes the Zydis® ODT fast-dissolve technology under an exclusive worldwide agreement with Catalent. Agents that modulate glutamate neurotransmission may have therapeutic potential in multiple disease states involving glutamate dysfunction, including ALS, Alzheimer’s disease, Rett syndrome, dementia, dystonia, tinnitus, anxiety disorders, and affective disorders like major depressive disorder. Biohaven is pursuing the use of glutamate modulating agents across several therapeutic indications.

The formal correspondence received from the FDA discussed clinical, nonclinical, and regulatory issues for BHV-0223, including the IND-opening clinical trial design and a proposed development plan for ALS. No issues were identified in the FDA response that would impede Biohaven’s planned bioequivalence trial in 2016. The key highlights from the PIND meeting feedback include:

- The FDA agreed that the 505(b)2 pathway is acceptable for BHV-0223 in ALS.
- The FDA agreed that no additional efficacy or toxicology studies are necessary for submission of the NDA.

Vlad Coric, M.D., CEO of Biohaven, commented, “We now have a clear regulatory path forward for BHV-0223 in ALS. The responses we received from FDA were aligned with our expectations, and no material issues were raised that would delay the timely initiation of our bioequivalence study. Our clinical program will expand upon our existing data with BHV-0223 and the goal will be to establish bioequivalence to the active pharmaceutical ingredient (riluzole) with lower doses of our new formulation. After we establish bioequivalence in the upcoming trial and demonstrate the advantages of this formulation to patients, we will be in position for a timely NDA submission. We believe that the enhanced formulation, dosage and route of administration of BHV-0223 will benefit patients with this devastating disease.”

The dosing of BHV-0223 proposed in the IND-opening clinical trial was based on the results of a successful Phase I trial (BHV223-101). This trial assessed the tolerability and unique pharmacokinetic characteristics of BHV-0223, in both single and multiple dosing in humans. Study BHV223-101 also compared the drug exposures of BHV-0223 and riluzole, the standard generic treatment for ALS.

Portage's CEO and Biohaven's Chairman, Declan Doogan M.D., stated, "The Biohaven team continues to demonstrate their ability to develop and execute on their strategy for BHV-0223. Biohaven will next take steps to prepare for an anticipated commercialization of the investigational agent upon successful results from the planned bioequivalence study. This will allow Biohaven to progress rapidly into the clinic and then to the market after NDA approval. The obligations are much less than a standard new drug application. We are very pleased with Portage investment in Biohaven a company with a great team and an exciting product line."

### ***About Biohaven***

Biohaven is a privately-held biopharmaceutical company engaged in the identification and development of clinical stage compounds targeting the glutamatergic system. The company has licensed intellectual property from Yale University and Massachusetts General Hospital. Biohaven is owned by a group of investors including Portage Biotech Inc. (OTC Market: PTGEF, Canadian Securities Exchange: PBT.U), Yale University and other private investors. The company's first drug candidate, BHV-0223, is a novel formulation of a glutamate-modulating agent, being developed under FDA 505(b)(2) guidelines. BHV-4157, a prodrug form of the same glutamate modulating agent, is being developed as a New Chemical Entity (NCE). The FDA cleared the company's Investigational New Drug application (IND) in August 2015 and BIOHAVEN has completed a PK study in humans with the final study report expected by 4Q2015 to enable the Phase 2/3 start in 2016. The company plans to advance other glutamatergic approaches and is actively exploring licenses for additional compounds.

### ***About Portage:***

Portage is engaged in identifying, financing and developing novel therapeutics in indications with high unmet medical need. Portage plans to add 5-7 other opportunities to its portfolio either by direct investment into a company, spinout from academia, or through the creation of an SPV with another company or management team

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 that has been shown to efficiently deliver an active pharmacological agent or cargo into a cell without disrupting the cell membrane. PPL will be advancing its lead candidate, PPL-003, to an Investigational New Drug (IND) application for the topical treatment of dry eye disease and uveitis. PPL recently completed a study in a rat model of dry eye disease in which a topical PPL-003 solution achieved highly significant efficacy and a more rapid onset of action than topical 0.1% dexamethasone.

Portage has also invested in Sentien Biotechnologies Inc., a Boston based private company developing an extracorporeal bioreactor for the delivery of cell therapies. This summer, Sentien completed a financing that will allow it to finish IND enabling studies and a Phase I trial.

For further information, contact Kam Shah, Chief Financial Officer, at [\(416\) 929-1806](tel: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.