

## NEWS RELEASE

### **PORTAGE'S BIOHAVEN ORPHAN DRUG DESIGNATION REQUEST GRANTED FOR THE TREATMENT OF SPINOCEREBELLAR ATAXIA**

**Toronto, Ontario, March 3, 2016** – Portage Biotech Inc. (“Portage”) (OTC Market: **PTGEF**, Canadian Securities Exchange: **PBT.U**), and Biohaven Pharmaceutical Holding Company Limited (Biohaven), are pleased to announce that the Food and Drug Administration (“FDA”) has granted the company’s orphan drug designation request covering BHV-0223 for the treatment of spinocerebellar ataxia. Spinocerebellar ataxia (SCA) is characterized clinically by progressive ataxia attributed to various etiologies. Ataxia is a complaint of loss of control of voluntary body movements and can involve unsteady gait, speech difficulties, and clumsiness, potentially progressing to the stage of difficulty with swallowing and breathing due to degenerative changes in the brain and spinal cord. There is no cure for the hereditary SCAs and lifespan can be significantly shortened due to complications related to neurologic deficits. It is estimated that 150,000 people in the United States are affected by hereditary ataxias. Treatment is supportive and no medications are currently approved for this potentially debilitating condition.

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.

“Modulation of cerebellar glutamate has potential for efficacy in populations with spinocerebellar ataxias, Biohaven sees an opportunity to leverage its glutamate targeting drug platform to address this important debilitating illness,” commented Robert Berman, M.D., CMO of Biohaven.

Vlad Coric, M.D., CEO of Biohaven, added, “Receiving the orphan drug designation request for spinocerebellar ataxia supports our global development strategy and goal of providing improved therapies for patients suffering from neurologic disorders with unmet need.”

Before the end of 2016, Biohaven expects to initiate a randomized clinical trial of its new chemical entity (NCE) glutamate modulating agent in patients with spinocerebellar ataxia. The study will enroll approximately 120 patients in the U.S. and will evaluate acute symptomatic treatment in this patient population. The trial is expected to support a New Drug Application (NDA) in SCA.

FDA orphan drug designation is intended to encourage companies to develop therapies for the treatment of diseases that affect fewer than 200,000 individuals in the United States. This designation

will provide Biohaven with 7 years of marketing exclusivity for BHV-0223 if approved by the FDA in such indication. Prior to FDA approval, orphan designation by the FDA provides the opportunity to obtain clinical trial tax credits for research, grant funding to defray development costs, and potential waiver of the FDA's application user fees.

Grey Bailey, Chairman of Portage commented, "This is a significant step in the development of the Biohaven portfolio". He also emphasized the importance of this for Portage shareholders.

### ***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.