Aeterna Zentaris (AEZS) Receives Positive CHMP Opinion of Macimorelin for Diagnosis of Adult Growth Hormone Deficiency

CHARLESTON, S.C., Nov. 19, 2018 -- Aeterna Zentaris Inc. (NASDAQ:AEZS) (TSX:AEZS), announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending a marketing authorization for macimorelin, an orally available ghrelin agonist, for diagnosis of adult growth hormone deficiency (AGHD). The recommendation will now be reviewed by the European Commission.

“We are pleased with the CHMP’s positive opinion of macimorelin for AGHD” said Michael V. Ward, Chief Executive Officer of Aeterna Zentaris.

Macimorelin is already approved by the Food and Drug Administration (FDA) in the United States for diagnosing AGHD and is commercially marketed as Macrilen™.

About AGHD

AGHD may occur in an adult subject who has a history of childhood onset growth hormone deficiency (GHD) or may occur during adulthood as an acquired condition. Considering a population of 510 million for the European Community, research based on incidence prevalence suggests that at least 35,000 adults could be afflicted with GHD.

About Macimorelin

Macimorelin stimulates the secretion of growth hormone from the pituitary gland into the circulatory system.

About Aeterna Zentaris Inc.

Aeterna Zentaris Inc. is a biopharmaceutical company focused on developing and commercializing, principally through out-licensing arrangements, Macrilen™ (macimorelin), an oral ghrelin receptor agonist, to be administered in the diagnosis of patients with adult growth hormone deficiency. On November 27, 2017 Aeterna Zentaris announced that the Marketing Authorization Application (MAA) for the use of Macrilen™ (macimorelin) for the evaluation of AGHD was accepted by the European Medicines Agency (EMA) for regulatory review. Aeterna Zentaris has licensed Macrilen™ (macimorelin) to a subsidiary of Strongbridge Biopharma plc in the United States and Canada. For more information, visit www.zentaris.com.

Forward-Looking Statements

This press release contains forward-looking statements (as defined by applicable securities legislation) made pursuant to the safe-harbor provision of the U.S. Securities Litigation Reform Act of 1995, which reflect our current expectations regarding future events. Forward-looking statements may include, but are not limited to statements preceded by, followed by, or that include the words "will," "expects," "believes," "intends," "would," "could," "may," "anticipates," and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known and unknown risks and uncertainties, including those discussed in this press release and in our Annual Report on Form 20-F, under the caption "Key Information - Risk Factors" filed with the relevant Canadian securities regulatory authorities in lieu of an annual information form and with the U.S. Securities and Exchange Commission. Known and unknown risks and uncertainties could cause our actual results to differ materially from those in forward-looking statements. Such risks and uncertainties include, among others, our now heavy dependence on the success of Macrilen™ (macimorelin) and related out-licensing arrangements and the continued availability of funds and resources to successfully launch the product, the ability of Aeterna

Zentaris to enter into out-licensing, development, manufacturing and marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect, reliance on third parties for the manufacturing and commercialization of our product candidates, potential disputes with third parties, leading to delays in or termination of the manufacturing, development, out-licensing or commercialization of our product candidates, or resulting in significant litigation or arbitration, and, more generally, uncertainties related to the regulatory process, our ability to efficiently commercialize or out-license Macrilen™ (macimorelin), the degree of market acceptance of Macrilen™ (macimorelin), our ability to obtain necessary approvals from the relevant regulatory authorities to enable us to use the desired brand names for our products, the impact of securities class action litigation, the litigation involving two of our former officers, or other litigation, on our cash flow, results of operations and financial position; any evaluation of potential strategic alternatives to maximize potential future growth and stakeholder value may not result in any such alternative being pursued, and even if pursued, may not result in the anticipated benefits, our ability to take advantage of business opportunities in the pharmaceutical industry, our ability to protect our intellectual property, the potential of liability arising from shareholder lawsuits and general changes in economic conditions. Investors should consult our quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties. Given these uncertainties and risk factors, readers are cautioned not to place undue reliance on these forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, unless required to do so by a governmental authority or applicable law.

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