



## **Aeterna Zentaris Announces European Licensing Agreement with Consilient Health Ltd. for Commercialization of Macimorelin**

**CHARLESTON, S.C., December 7, 2020** -- Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZS), through its wholly-owned subsidiary, ("Aeterna" or the "Company"), a specialty biopharmaceutical company commercializing and developing therapeutics and diagnostic tests, today announced that it has entered into an exclusive licensing agreement (the "Agreement") with Consilient Health, Ltd. ("CH" or "Consilient Health"), a privately owned pharmaceutical company focused on commercializing medicines in Europe and Middle East, for the commercialization in Europe and the United Kingdom of macimorelin, Aeterna's orally available ghrelin agonist, in any diagnostic application, including the diagnosis of patients with adult growth hormone deficiency ("AGHD") and, subject to receipt of regulatory approval, childhood-onset growth hormone deficiency ("CGHD").

Under the terms of the Agreement, CH will be responsible for obtaining pricing and reimbursement approval in the European economic area and the United Kingdom, as well as bearing the regulatory cost for the label extension for pediatric use pending successful outcome of the upcoming safety and efficacy study, AEZS-130-P02 ("Study P02"), evaluating macimorelin for the diagnosis of CGHD. This pivotal Phase 3 Study P02 is expected to be initiated in Q1 of 2021. Aeterna and Consilient Health have also entered into a separate commercial supply agreement under which Consilient Health will purchase macimorelin from Aeterna and Aeterna will be responsible for supply and product quality. Aeterna will continue to maintain control of its patents covering macimorelin in Europe and the United Kingdom.

As agreed, Consilient Health will make an up-front payment to Aeterna of Euro 1 million and will pay to Aeterna royalties on net sales of macimorelin ranging from 10% to 20% depending on the level of net sales achieved by Consilient Health in the particular year. Aeterna will also be eligible to receive milestone payments associated with the achievement of pricing and reimbursement approvals in certain countries in Europe and in the United Kingdom, upon approval of macimorelin in CGHD, and on the attainment by Consilient Health of other sales based events.

"This license agreement represents another significant milestone for the Company as we continue to secure and bolster our portfolio of marketing partners for macimorelin in key markets. As a synergistic partner of choice with insight and commercialization capabilities, we believe that Consilient Health brings noteworthy expertise that is the right fit for Aeterna. We are grateful for their partnership and look forward to leveraging their

experience in driving innovative marketing to our international distribution network for macimorelin,” commented Dr. Klaus Paulini, Chief Executive Officer of Aeterna Zentaris.

Commenting on the agreement, Ahmed Al-Derzi, Consilient Health’s CEO stated, “We are delighted to build this partnership with Aeterna Zentaris for macimorelin. Not only does the brand further strengthen our growing offering to endocrinology specialists and their patients but it also strengthens CH’s position across Europe. Macimorelin is an exciting innovation in the field of growth hormone deficiency.”

In addition to advancing its pediatric program, Aeterna is actively pursuing its business development activities with the goal of securing marketing partners for macimorelin for the diagnosis of growth hormone deficiency in additional markets where the Company does not already have partnership agreements.

The Agreement will be filed on SEDAR at [www.sedar.com](http://www.sedar.com). The foregoing description of the terms of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement.

### **About Consilient Health**

Consilient Health is a pharmaceutical company with a rich heritage of commercializing products in areas such as women’s health, urology and endocrinology.

In all of Consilient Health’s planning, the patient is very much at the center. Considering the needs of both the healthcare professional and the payer, as well as those of the patient is key to its commercial success.

Established in 2005, Consilient Health’s success has been built on cultivating strong partnerships with pharma companies and on ensuring access and then marketing prescription healthcare products across Europe and the Middle East.

### **About Macimorelin**

Macimorelin, a ghrelin agonist, is an orally active small molecule that stimulates the secretion of growth hormone from the pituitary gland. Stimulated growth hormone levels are measured in blood samples after oral administration of macimorelin for the assessment of GHD.

In December 2017, the United States Food and Drug Administration (“FDA”) granted Aeterna Zentaris marketing approval for macimorelin to be used in the diagnosis of patients with adult growth hormone deficiency. Macrilen™ has been granted Orphan Drug designation by the FDA for diagnosis of AGHD. In January 2019, the European Commission granted marketing authorization for macimorelin to Aeterna Zentaris for diagnosis of growth hormone deficiency in adults. In March 2017, the Pediatric Committee

of the EMA agreed to the Company's PIP for macimorelin, a prerequisite for filing a marketing authorization application for any new medicinal product in Europe.

### **About Aeterna Zentaris Inc.**

Aeterna Zentaris Inc. is a specialty biopharmaceutical company commercializing and developing therapeutics and diagnostic tests. The Company's lead product, macimorelin, is the first and only U.S. FDA and European Commission approved oral test indicated for the diagnosis of adult growth hormone deficiency (AGHD). Macimorelin is currently marketed in the United States under the tradename Macrilen™ through a license agreement with Novo Nordisk where Aeterna Zentaris receives royalties on sales. According to a commercialization and supply agreement, MegaPharm Ltd. will seek regulatory approval and then commercialize macimorelin in Israel and the Palestinian Authority. Additionally, upon receipt of pricing and reimbursement approvals, Aeterna expects that macimorelin will be marketed in Europe and the United Kingdom through a recently established license agreement with Consilient Health Ltd and Aeterna Zentaris will receive royalties on sales and other potential payments.

Aeterna Zentaris is also leveraging the clinical success and compelling safety profile of macimorelin to develop it for the diagnosis of childhood-onset growth hormone deficiency (CGHD), an area of significant unmet need.

The Company is actively pursuing business development opportunities for the commercialization of macimorelin in Europe and the rest of the world, in addition to other non-strategic assets to monetize their value. For more information, please visit [www.zentaris.com](http://www.zentaris.com) and connect with the Company on [Twitter](#), [LinkedIn](#) and [Facebook](#).

### **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 include those relating to the Company obtaining approval of macimorelin for CGHD, the Company's ability to secure marketing partners for macimorelin in other key markets, the timing of the commencement of the CGHD Study P02, and 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 ability to raise capital and obtain financing to continue our currently planned operations, our ability to continue to list our

Common Shares on the NASDAQ, 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 commercialize the product, including our heavy reliance on the success of the License Agreement with Novo Nordisk, the global instability due to the global pandemic of COVID-19, and its unknown potential effect on our planned operations, including studies, our ability to enter into out-licensing, development, manufacturing, marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect, our reliance on third parties for the manufacturing and commercialization of Macrilen™ (macimorelin), 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, uncertainties related to the regulatory process, unforeseen global instability, including the instability due to the global pandemic of the novel coronavirus, our ability to efficiently commercialize or out-license Macrilen™ (macimorelin), our reliance on the success of the pediatric clinical trial in the European Union (“E.U.”) and U.S. for 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 product, our ability to successfully negotiate pricing and reimbursement in key markets in the E.U. for Macrilen™ (macimorelin), any evaluation of potential strategic alternatives to maximize potential future growth and shareholder 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, and 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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