

Waverley Pharma Announces Tentative ANDA Approval for Pemetrexed in the United States

WINNIPEG, MB, Nov. 12, 2020 /CNW/ - Waverley Pharma Inc. ("Waverley Pharma" or the "Company") (TSXV: WAVE), an emerging Canadian pharmaceutical company, is pleased to announce that the Company has obtained tentative approval of its Abbreviated New Drug Application (ANDA) for Pemetrexed for Injection, 100 mg and 500 mg (formerly known as "WAV-101") in the United States (US). The tentative ANDA approval indicates that the technical requirements for approval have been met but approval can not be made effective or marketing begin until the patent on the reference listed drug has expired, which is projected to occur in 2022.

About Pemetrexed

Pemetrexed is an injectable chemotherapy product used in the treatment of pleural mesothelioma and non-small cell lung cancer along with other indications. In addition to obtaining tentative ANDA approval in the US, the Company has obtained marketing authorization for this product in numerous European countries and is in the process of filing for market authorization in additional countries across Europe.

About Waverley Pharma

Waverley Pharma is an emerging pharmaceutical company focused on the development and commercialization of safe, effective, and affordable cancer therapeutics in the European Union, United Kingdom and North American market. The Company, through its subsidiary, is currently selling three generic oncology products in the United Kingdom, namely capecitabine, temozolomide and erlotinib. In addition, the Company is developing two generic oncology products in Europe, namely pemetrexed and bortezomib and additional products in the United States. Waverley Pharma is committed to providing patients with affordable prescription medicines that lower healthcare costs and provide a better quality of life. For more information on Waverley Pharma please visit www.waverleypharma.com.

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Forward Looking Information: *Statements contained in this press release that are not statements of historical fact, including, without limitation, statements containing the words "believes", "may", "plans", "will", "estimates", "continues", "anticipates", "intends", "expects" and similar expressions, may constitute "forward-looking information" within the meaning of applicable Canadian and U.S. federal securities laws (such forward-looking information and forward-looking statements are hereinafter collectively referred to as "forward-looking statements"). Forward-looking statements include the potential patent expiry date of the reference listed drug and other estimates, analysis and opinions of management of the Company made in light of its experience and its perception of trends, current conditions and expected developments, as well as other factors which the Company believes to be relevant and reasonable in the circumstances. Inherent in forward-looking statements are known and unknown risks, uncertainties and other factors beyond the Company's ability to predict or control that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements, and as such, readers are cautioned not to place undue reliance on forward-looking statements. Such risk factors include, among others, the Company's potential product revenues, stage of development, additional capital requirements, risks associated with obtaining regulatory approval to market the Company's products, the ability to protect its intellectual*

property, dependence upon collaborative partners, changes in government regulation or regulatory approval processes, and rapid technological change in the industry. Such statements are based on a number of assumptions which may prove to be incorrect, including, but not limited to, assumptions about: general business and economic conditions; the impact of changes in Canadian-US dollar and other foreign exchange rates on the Company's revenues, costs and results; the timing of the receipt of regulatory and governmental approvals for the Company's research and development projects; the availability of financing for the Company's commercial operations and/or research and development projects, or the availability of financing on reasonable terms; the uncertainties associated with the acceptance and demand for new products and market competition. The foregoing list of important factors and assumptions is not exhaustive. The Company undertakes no obligation to update publicly or otherwise revise any forward-looking statements or the foregoing list of factors, other than as may be required by applicable legislation. Additional discussion regarding the risks and uncertainties relating to the Company and its business can be found in the Company's other filings with the applicable Canadian securities regulatory authorities.

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