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Fennec Pharmaceuticals and Norgine Enter into Exclusive Licensing Agreement to Commercialize PEDMARQSI in Europe, Australia, and New Zealand

Research Triangle Park, N.C. and Uxbridge, England (ots/PRNewswire) -

Agreement pairs Norgine's commercial expertise and leading European footprint with PEDMARQSI™, the first and only approved therapy in the European Union and U.K. for reducing the risk of cisplatin-induced hearing loss in pediatric patients with localized, non-metastatic solid tumors

Fennec will receive €40 million in upfront and up to €210 million in additional commercial and regulatory milestones, and tiered royalties up to the mid-twenties

Enhances Norgine's commitment to bringing transformative therapies to patients in Europe, U.K., Australia, and New Zealand who currently do not have access to a therapy to treat this life altering condition

Fennec Pharmaceuticals Inc. (NASDAQ: FENC; TSX: FRX), a commercial stage specialty pharmaceutical company, and Norgine, a leading European specialist pharmaceutical company, today announced an exclusive licensing agreement under which Norgine will commercialize *PEDMARQSI®* in Europe, Australia and New Zealand. *PEDMARQSI* is the first and only approved therapy in the EU and U.K. for the prevention of ototoxicity (hearing loss) induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic solid tumors.

Under the terms of the licensing agreement, Fennec will receive €40 million in upfront consideration and up to €210 million in additional commercial and regulatory milestone payments and double-digit tiered royalties on net sales of *PEDMARQSI* in the licensed territories up to the mid-twenties. Norgine will be responsible for all commercialization activities in the licensed territories and will hold all marketing authorizations in the licensed territories.

It is estimated that more than 5,000 pediatric patients annually are eligible for platinum-based chemotherapy in Europe. *PEDMARQSI* was granted EU marketing authorization by the European Commission in June 2023, and received UK approval from the MHRA in October 2023. Approvals were based on safety and efficacy data from two open-label, randomized Phase 3 trials, SIOPEL 6 (pivotal) and Clinical Oncology Group [COG] Protocol ACCL0431. The studies compared *PEDMARQSI* plus cisplatin-based regimens to cisplatin-based regimens alone for the reduction of cisplatin-induced hearing loss in pediatric patients. *PEDMARQSI* holds eight years plus two years of data and market protection in Europe based on its Pediatric Use Marketing Authorization. Approval in Switzerland, Australia and New Zealand will also be pursued.

The first study (SIOPEL-6) involved 114 children with hepatoblastoma (a cancer of the liver), with an average age of about 19 months. The results showed that 35% (20 out of 57) of children who received Pedmarqsi 6 hours after each dose of cisplatin developed hearing loss compared with 67% (35 out of 52) of children who only received cisplatin. The second study involved 125 children aged 1 month to 18 years with different types of cancer, including hepatoblastoma, neuroblastoma (a cancer of immature nerve cells) and tumours of the central nervous system. The study found that hearing loss was experienced by 29% (14 out of 49) of children who received Pedmarqsi after each cisplatin dose compared with 56% (31 out of 55) of those who received only cisplatin.

"We are delighted to partner with Norgine, who shares our belief in the potential of PEDMARQSI to mitigate the risk of permanent and irreversible hearing loss that can occur in pediatric patients treated with cisplatin. Further, this partnership is an important step in achieving our mission of expanding PEDMARQSI to patients across the globe who are at risk of suffering from cisplatin-induced ototoxicity," said Rosty Raykov, Chief Executive Officer of Fennec Pharmaceuticals. "From a deal perspective, the terms provided us many important benefits, including an upfront payment further solidifying our balance sheet, attractive economic terms providing meaningful participation in the ex-US success of PEDMARQSI and an experienced partner to successfully launch PEDMARQSI in the licensed territory."

Chris Bath, Chief Executive Officer of Norgine, said "We are thrilled to announce our partnership with Fennec, to bring this vital medicine to pediatric patients who are being treated with cisplatin, across Europe and ANZ. We look forward to working with the Fennec team and launching PEDMARQSI in our territories in the coming months, establishing it as the standard of care in this critical patient population with high unmet need. This important milestone for our company builds on our 30 year track record of creating partnerships of enduring value and further underscores Norgine's position as the specialty pharma partner of choice across Europe and ANZ."

Moelis & Company LLC acted as financial advisor, and LaBarge Weinstein LLP acted as legal advisor to Fennec. Arnold & Porter acted as legal advisor to Norgine.

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK® and *PEDMARQSI®* to reduce the risk of platinum-induced ototoxicity in pediatric patients. PEDMARK received FDA

approval in September 2022 and European Commission Marketing Authorization in June 2023 for *PEDMARQSI*. Further, PEDMARQSI received U.K. approval in October 2023. PEDMARK has received Orphan Drug Exclusivity in the U.S. for seven years of market protection and *PEDMARQSI* has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. For more information, please visit www.fennecpharma.com.

About Norgine

Norgine is a leading European specialist pharmaceutical company that has been bringing transformative medicines to patients for over a century. Commitment to transforming people's lives drives everything Norgine does with fully integrated infrastructure and exceptional partnership approach enabling creative solutions to bring life-changing medicines to patients that they may not otherwise be able to access. Norgine is proud to have helped more than 25 million patients annually around the world and generated over €500 million in net product sales in 2023.

Norgine has a direct presence in 18 European countries, as well as Australia and New Zealand and has a strong global network of partnerships in non-Norgine markets. Norgine possesses a flexible and fully integrated pharmaceutical business, with manufacturing (Hengoed, Wales and Dreux, France), third party supply networks and significant product development capabilities, in addition to sales and marketing infrastructure.

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Forward Looking Statements

Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK® and PEDMARQSI®, the market opportunity for and market impact of PEDMARK and PEDMARQSI, its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2022. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

For a more detailed discussion of related risk factors, please refer to our public filings available at www.sec.gov and www.sedar.com.

PEDMARK®, PEDMARQSI® and Fennec® are registered trademarks of Fennec Pharmaceuticals Inc.

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