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RedHill Biopharma and IntelGenx Announce RIZAPORT® Commercialization Term Sheet with Pharmatronic Co. for Korea

- ▮ **RIZAPORT® (5 mg and 10 mg) was granted marketing approval in Germany under the European Decentralized Procedure (DCP)**
- ▮ **This binding term sheet for the license of RIZAPORT® in South Korea follows a recent commercialization agreement for Spain with Grupo JUSTE S.A.Q.F, who recently filed a national Marketing Authorization Application (MAA) for RIZAPORT® in Spain**
- ▮ **RedHill and IntelGenx expect to re-submit the RIZAPORT® U.S. New Drug Application (NDA) to the FDA in the first half of 2017 and subsequently receive a new PDUFA date**

TEL-AVIV, Israel, Sept. 21, 2016 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, together with IntelGenx Corp. (TSX-V:IGX) (OTCQX:IGXT) ("IntelGenx"), a Canadian drug delivery company focused on oral drug delivery, today announced that they have entered into a binding term sheet with Pharmatronic Co. granting Pharmatronic Co. the exclusive license to commercialize RIZAPORT® in the Republic of Korea (South Korea). RIZAPORT® is a proprietary oral thin film formulation of rizatriptan for the treatment of acute migraines.

Subject to satisfaction of remaining conditions, the parties will endeavor to enter into a definitive agreement within 60 days of the execution of the term sheet.

Pursuant to the signing of a definitive agreement, RedHill will grant Pharmatronic Co. the exclusive rights to register and commercialize RIZAPORT® in South Korea. Under the term sheet, RedHill and IntelGenx are to receive an upfront payment and will be eligible to receive additional milestone payments upon achievement of certain predefined regulatory and commercial targets, as well as tiered royalties. Financial terms of the term sheet were not disclosed. The initial term of the definitive agreement is expected to be ten years from the date of first commercial sale with an automatic renewal of an additional two years. Commercial launch in South Korea is estimated to take place in the first quarter of 2019.

Mr. Adi Frish, RedHill's Senior VP Business Development & Licensing, said: "We are very pleased to enter into this term sheet with Pharmatronic Co. This is potentially the second territorial license for the commercialization of RIZAPORT®, following the license agreement with Grupo JUSTE for Spain, where a marketing application for RIZAPORT® has recently been submitted. We continue to work diligently to maximize the worldwide potential of this unique migraine drug and are in discussions with multiple potential commercialization partners. Pharmatronic Co. holds a growing portfolio of neurology-focused drugs and is experienced in commercializing migraine products in South Korea. With its unique dissolvable oral thin film delivery form and pleasant flavoring, we are confident that RIZAPORT® should be a welcomed therapeutic alternative for many migraine patients in Korea."

RIZAPORT® (5 mg and 10 mg) was granted marketing authorization by the Federal Institute for Drugs and Medical Devices of Germany (BfArM) under the European Decentralized Procedure (DCP), in which Germany served as the Reference Member State for other European Union (EU) countries. This authorization was the first national marketing approval of RIZAPORT® and a first commercialization agreement was recently signed with Grupo JUSTE S.A.Q.F for Spain and additional potential territories. A national Marketing Authorization Application (MAA) for RIZAPORT® was recently submitted by Grupo JUSTE S.A.Q.F in Spain under the European DCP.

RedHill and IntelGenx expect to re-submit the RIZAPORT® New Drug Application (NDA) to the FDA in the first half of 2017 and subsequently receive a new PDUFA (Prescription Drug User Fee Act) date and are currently in discussions with potential commercialization partners for the U.S. market.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105** - an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study; (ii) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA® (RHB-102)** - a once-daily oral pill formulation of ondansetron with an ongoing Phase III study for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106** - an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640)** - a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON** - a Phase II-stage first-in-class, orally-administered uPA inhibitor, targeting gastrointestinal and other solid tumors; (vii) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class, orally-administered Hsp27 inhibitor, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT® (RHB-103)** - an oral thin film formulation of rizatriptan for acute migraines, with a U.S. NDA currently under discussion with the FDA and marketing authorization received in Germany in October 2015; and (ix) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol.

About Pharmatronic Co:

Pharmatronic Co. is a pharmaceutical company headquartered in Seoul, Korea and distributing exclusively licensed pharmaceutical products with innovative sales and marketing know-how. Since established in 2005, Pharmatronic Co. has focused R&D and marketing resources on the specialized target field of neurology, ENT and urology, building a strong image of a leading provider in the pharmaceutical and healthcare industry.

About IntelGenx:

IntelGenx is a leading oral drug delivery company focused on the development and manufacturing of innovative pharmaceutical oral films based on its proprietary VersaFilm™ technology platform. Established in 2003, the Montreal-based company is listed on the TSX-V and OTC-QX.

IntelGenx highly skilled team provides comprehensive pharmaceuticals services to pharmaceutical partners, including R&D, analytical method development, clinical monitoring, IP and regulatory services. IntelGenx state-of-the art manufacturing facility, established for the VersaFilm™ technology platform, supports lab-scale to pilot and commercial-scale production, offering full service capabilities to our clients. More information is available about the company at: www.intelgenx.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; (iii) the extent and number of additional studies that the Company may be required to conduct and the Company's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings, approvals and feedback; (iv) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates; (v) the Company's ability to establish and maintain corporate collaborations; (vi) the Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (vii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) the impact of the political and security situation in Israel on the Company's business. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on February 25, 2016. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement unless required by law.

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