

Health Canada Accepts for Review Medexus's New Drug Submission for Topical Terbinafine

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Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - January 8, 2024) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) today announced that Health Canada recently accepted for review Medexus's new drug submission, or NDS, for terbinafine hydrochloride nail lacquer to treat fungal nail infections.

"Health Canada's commitment to review our NDS brings us a step closer to making topical terbinafine a viable treatment option for Canadians," said Richard Labelle, Medexus's General Manager-Canadian Operations. "Topical terbinafine is an excellent strategic fit for our leading allergy/dermatology business, and we look forward to putting our institutional knowledge to work as we target a commercial launch in the first half of calendar year 2025."

Topical terbinafine has been widely used in other markets to treat fungal nail infections. Medexus's NDS for topical terbinafine seeks Health Canada approval for a distinctive once-a week treatment regimen. If and when approved, the product will enter the Canadian topical fungicides market that is estimated to be C\$88 million on an annual basis.*

** Source: IQVIA Canadian drugstore and hospital purchases, September 2023 MAT.*

About Medexus

Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform and a growing portfolio of innovative and rare disease treatment solutions. Medexus's current focus is on the therapeutic areas of oncology, hematology, rheumatology, auto-immune diseases, allergy, and dermatology. For more information about Medexus and its product portfolio, please see the company's corporate website at www.medexus.com and its filings on SEDAR+ at www.sedarplus.com.

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Forward-looking statements

Certain statements made in this news release contain forward-looking information within the meaning of applicable securities laws, also known and/or referred to as "forward-looking information" or "forward-looking statements". The words "anticipates", "believes", "expects", "will", "plans", "potential", and similar words, phrases, or expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words, phrases, or expressions. Specific forward-looking statements contained in this news release include, but are not limited to, statements regarding the potential benefits of terbinafine hydrochloride; the occurrence, timing, and expected outcome of the Health Canada review process for the NDS for terbinafine hydrochloride discussed in this news release; if approved by Health Canada, the expected timing of any commercial launch of terbinafine hydrochloride discussed in this news release in Canada and related expectations

regarding the product's prospects; and the potential competitive position of terbinafine hydrochloride discussed in this news release and anticipated trends and potential challenges in the market in which the product is expected to compete. These statements are based on factors or assumptions that were applied in drawing a conclusion or making a forecast or projection, including assumptions based on historical trends, current conditions, and expected future developments. Since forward-looking statements relate to future events and conditions, by their very nature they require making assumptions and involve inherent risks and uncertainties. Medexus cautions that, although the assumptions are believed to be reasonable in the circumstances, these risks and uncertainties mean that actual results may differ, and may differ materially, from the expectations contemplated by the forward-looking statements. Material risk factors include, but are not limited to, those set out in Medexus's materials filed with the Canadian securities regulatory authorities from time to time, including Medexus's most recent annual information form and management's discussion and analysis. In addition, specific risks and uncertainties relevant to the content of this news release include, among other things, the uncertainties inherent in research initiatives and regulatory review processes, including the possibility of unfavorable new data and further analyses of existing data; the risk that data and regulatory submissions are subject to differing interpretations and assessments by regulatory authorities and/or other relevant third parties; and whether regulatory authorities and/or other relevant third parties will be satisfied with the design and methodology of and results from relevant studies and/or the content of relevant regulatory submissions, all of which will depend on many factors, including determinations as to whether the product's benefits outweigh its known risks. Accordingly, undue reliance should not be placed on these forward-looking statements, which are made only as of the date of this news release. Other than as specifically required by law, Medexus undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.

Additional notes

Terbinafine hydrochloride nail lacquer, as discussed in this news release, is not approved by Health Canada for sale and use in Canada. Medexus makes no representation that terbinafine hydrochloride is appropriate for, or authorized for sale to or use by, persons who are located either in or outside Canada. Terbinafine hydrochloride is currently the subject of a regulatory review process with Health Canada. Medexus holds exclusive commercialization rights to terbinafine hydrochloride nail lacquer supplied by Polichem, an Almirall group company focused on medical dermatological treatments for skin health, in Canada.

The information in this news release is provided for informational purposes to investors in Medexus securities.



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