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Medexus Highlights Data on Trecondyv (Treosulfan) Presented at MDS 2023

Princess Margaret Cancer Center's retrospective analysis found a 30% improvement (83.2% vs 53.2%) in one-year overall survival for patients treated with treosulfan, among other positive findings

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - June 13, 2023) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) is pleased to highlight positive new data on treosulfan that researchers at Toronto's Princess Margaret Hospital (**PMH**) recently presented at MDS 2023, the 17th annual International Congress on Myelodysplastic Syndromes, held in Marseille, France. The study, a retrospective analysis of patient outcomes, further confirms Medexus's optimism regarding treosulfan's potential positive impact in both Canada and the United States.

The study found that reduced toxicity conditioning (**RTC**) with fludarabine-treosulfan (**FT**) improves transplant outcomes in myeloablative conditioning (**MAC**) ineligible patients with myelodysplastic syndrome (**MDS**) who receive graft-vs-host disease (**GVHD**) prophylaxis with dual T-cell depletion (**TCD**). Notably, the study found a 30% improvement (83.2% vs 53.2%) in one-year overall survival for patients treated with treosulfan, among other positive findings. See "About the study" below for additional information about the study's methods, results, and conclusions, including information about the study's design and a summary of selected statistical information.

"We are very encouraged by these new results of PMH's study, which are consistent with previous studies and further demonstrate the potential benefits of treosulfan," said Ken d'Entremont, Medexus's Chief Executive Officer. "We see this latest evidence as yet another important indicator of this product's prospects, including because we view these results as equally relevant to patient communities in the United States market."

"Clinicians should always make the best choice possible for their patients, so we are very pleased with the data we presented at MDS 2023, as it further underscores the clinical and therapeutic utility of treosulfan," added Dr Ivan Pasic from PMH.

The full abstract, which includes further discussion of the study's design and findings, was published in the Leukemia Research journal and is available at the following link:

https://doi.org/10.1016/j.leukres.2023.107131

The MDS 2023 presentation is substantially consistent with the previously published final study results and analysis of the pivotal phase 3 clinical trial of treosulfan, which Medexus announced in June 2022. Among other things, that earlier study demonstrated clinically relevant superiority of treosulfan over a reduced-intensity conditioning busulfan regimen with regard to event-free survival, that study's primary endpoint.

"We remain excited about the prospect of a treosulfan approval in the United States and about treosulfan's significant potential in the US market," Mr d'Entremont concluded. "If approved by the FDA, we expect that treosulfan would have a meaningful impact on Medexus's total revenue. For reference, as one indicator of the potential market opportunity, we estimate that a market-leading product in the United States generated approximately US$126 million in peak annual revenue before genericization."

About Trecondyv™ (treosulfan)

Treosulfan is part of a preparative regimen for allogeneic hematopoietic stem cell transplantation, to be used in combination with fludarabine, used in treating eligible patients with acute myeloid leukemia and myelodysplastic syndromes.

Final study results and analysis of the pivotal phase 3 clinical trial of treosulfan conducted by medac GmbH, which was published in the American Journal of Hematology, concluded that the study demonstrates clinically relevant superiority of treosulfan over a widely applied "reduced-intensity conditioning" busulfan regimen with regard to its primary endpoint, event-free survival. The publication also includes favorable conclusions on two key secondary endpoints, finding that overall survival with treosulfan was superior compared to busulfan and that non-relapse mortality for patients in the treosulfan arm was lower than for patients in the busulfan arm. For more information about the study and the publication, including a link to the full publication, see Medexus's June 6, 2022 press release, available via the Investors section of Medexus's corporate website.

During the phase 3 clinical trial of treosulfan, treatment emergent adverse events (**TEAEs**) were reported by 92.6% of patients in the treosulfan treatment group. TEAEs were most commonly reported in the system organ classes, or SOCs, of "Gastrointestinal disorders", "General disorders and administration site conditions", and "Musculoskeletal and connective tissue disorders". TEAEs of at least CTCAE Grade III were reported by 54.8% of patients in the treosulfan treatment group. Severe adverse events were reported by 8.5% of patients in the treosulfan treatment group.

For more information about Trecondyv™ (treosulfan), including important safety information, see the product monograph, which is available on Health Canada's website at: https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=100678.

Treosulfan is approved by Health Canada for sale and use in Canada only and is not intended for export outside Canada. Medexus makes no representation that treosulfan is appropriate for, or authorized for sale to or use by, persons who are not located in Canada. Treosulfan is currently the subject of a regulatory review process with the US Food and Drug Administration. Medexus holds exclusive commercialization rights to treosulfan in Canada and the United States.

About the study

PMH researchers determined that several studies have demonstrated favorable outcomes with FT RTC in MAC-ineligible patients with MDS undergoing allogeneic hematopoietic cell transplantation, but that none of these studies included individuals who received dual TCD for GVHD prophylaxis. The researchers therefore retrospectively analyzed outcomes with FT conditioning in a cohort of MAC-ineligible MDS patients who received dual TCD for GVHD

prophylaxis.

The researchers compared transplant outcomes among 29 MDS patients who received FT to a propensity-score matched cohort of 58 subjects who received conditioning with fludarabine, busulfan, and 200 cGy (or centigray) of total body irradiation (**FBT200**). The study concluded that RTC with FT improves transplant outcomes in MAC-ineligible patients with MDS who receive GVHD prophylaxis with dual TCD.

One-year overall survival (**OS**), relapse-free survival (**RFS**), GVHD- and relapse-free survival (**GRFS**), transplant related mortality, and relapse in FT and FBT200 patients were: 83.2% vs 53.2% (P=0.003), 76.1% vs 42.7% (P=0.005), 72.4% vs 37.9% (P=0.003), 8.6% vs 33.0% (P=0.01), and 15.3% vs 24.3% (P=0.38). There was no difference in day-100 grade 2-4 or 3-4 acute GVHD or one-year all-grade chronic GVHD between the two groups: 20.8% vs 15.5% (P=0.42), 0% vs 8.6% (P=0.37), and 17.5% vs 29.8% (P=0 .24). FT was associated with superior OS, RFS, and GRFS in multivariate analysis.

Median follow-up for the whole cohort was 20.5 months (range: 3.1-77.4). The groups were well-matched; FT subjects included more men (P=0.01) and received a lower median CD34 cell dose (P=0.03). In both FT and FBT200 groups, dual TCD was the most common form of GVHD prophylaxis: 93.1% and 91.4% (P=1.0).

Medexus provided partial support for the research through supply of treosulfan.

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.sedar.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 (**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 treosulfan (currently marketed in Canada as Trecondyv™), the occurrence, timing, and expected outcome of the FDA review process for treosulfan, and expectations regarding the product's prospects if approved by the FDA. 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, and, in particular, Medexus's interpretation and assessment of the data presented by Medexus as summarized in this news release. 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 it is believed that the assumptions are reasonable in the circumstances, these risks and uncertainties give rise to the possibility that actual results may differ materially from the expectations set out in 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 (including the possibility of unfavorable new data and further analyses of existing data); the risk that data 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 the relevant study, which will depend on many factors, including determinations as to whether the product's benefits outweigh its known risks and determinations of the product's efficacy and cost-effectiveness in the context of a given facility (which varies by facility type). 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

Trecondyv™ (treosulfan), as discussed in this news release, is a Canadian trademark of medac GmbH. Solely for convenience, trademarks may appear without the "™", "®", or similar symbols. Each such reference should be read as though it appears with the relevant symbol. Any such references are not intended to indicate, in any way, that the holder or holders of the relevant intellectual property rights will not assert those rights to the fullest extent under applicable law.

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

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