Miravo Healthcare™ Announces Receipt of Health Canada Notice of Compliance for the Pediatric Use of Blexten®

- Blexten Label Expanded to Include Ages as Young as 4 Years Old –
- Includes Approval of 2.5mg/mL Oral Solution and 10mg orodispersible (Quick Melt) Tablet Formats -
- Commercial Availability of Pediatric Formats Anticipated During Q1 2022 -

Mississauga, Ontario, Canada – August 12, 2021 – Nuvo Pharmaceuticals Inc. (TSX:MRV; OTCQX:MRVFF) d/b/a Miravo Healthcare (Miravo or the Company), a Canadian-focused healthcare company with global reach and a diversified portfolio of commercial products, today announced Health Canada has issued a Notice of Compliance (NOC) in relation to the Company’s Supplement to New Drug Submission for the pediatric use of Blexten. The pediatric use includes the approval of two new dosage formats; a 2.5mg/mL oral solution and a 10mg Quick Melt tablet. Upon commercial launch, which is anticipated for Q1 2022, the pediatric formats will be available to patients with a prescription from their healthcare provider.

“The expansion of the Health Canada approved Blexten label for use in children as young as 4 years old means that Blexten can now be the single prescription antihistamine of choice for most Canadian allergy and urticaria patients. The issuance of this NOC increases the treatable patient population and provides patients with two additional convenient dosing formats; an oral solution and Quick Melt tablets, in addition to our existing 20mg tablet format that is available for patients 12 years of age and older. This is a great milestone for the Blexten franchise and I would like to recognize and thank our regulatory, scientific, tech ops and commercial teams for the hard work that went into obtaining this approval and working toward launch,” said Mr. Jesse Ledger, Miravo’s President and Chief Executive Officer.

About Blexten

Blexten is a second-generation antihistamine drug for the symptomatic relief of allergic rhinitis and chronic spontaneous urticaria. Blexten exerts its effect through its highly selective inhibition of peripheral histamine H1 receptors and has an efficacy comparable to cetirizine and desloratadine. In comparative studies, Blexten demonstrated somnolence rates similar to placebo representing a potentially non-sedating effect at therapeutic doses. It was developed in Spain by Faes Farma, S.A. (Faes). Bilastine, (the active ingredient in Blexten), is approved in Canada and over 100 countries worldwide, including Japan and most European countries. In 2014, Miravo entered into an exclusive license and supply agreement with Faes for the exclusive right to sell bilastine in Canada, which is sold under the brand name Blexten. The exclusive license is inclusive of prescription and non-prescription rights for Blexten, as well as adult and pediatric presentations in Canada. In April 2016, Health Canada approved Blexten (bilastine 20 mg oral tablet) for the treatment of the symptoms of seasonal allergic rhinitis and chronic spontaneous urticaria (such as itchiness and hives).

About Miravo Healthcare

Miravo is a Canadian focused, healthcare company with global reach and a diversified portfolio of commercial products. The Company’s products target several therapeutic areas, including pain, allergy, neurology and dermatology. The Company’s strategy is to in-license and acquire growth-oriented, complementary products for Canadian and international markets. Miravo’s head office is located in Mississauga, Ontario, Canada, the international operations are located in Dublin, Ireland and the Company’s manufacturing facility is located in Varennes, Québec, Canada. The Varennes facility operates in a Good Manufacturing Practices (GMP) environment respecting the U.S, Canada and E.U. GMP regulations and is regularly inspected by Health Canada and the U.S. Food and Drug Administration. For additional information, please visit www.miravohealthcare.com.
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Forward-Looking Statements
This press release contains “forward-looking information” as defined under Canadian securities laws (collectively, “forward-looking statements”). The words “plans”, “expects”, “does not expect”, “goals”, “seek”, “strategy”, “future”, “estimates”, “intends”, “anticipates”, “does not anticipate”, “projected”, “believes” or variations of such words and phrases or statements to the effect that certain actions, events or results “may”, “will”, “could”, “would”, “should”, “might”, “likely”, “occur”, “be achieved” or “continue” and similar expressions identify forward-looking statements. In addition, any statements that refer to expectations, intentions, projections or other characterizations of future events or circumstances contain forward-looking statements. These forward-looking statements include statements regarding the anticipated commercial launch of the pediatric use of Blexten.

Forward-looking statements are not historical facts but instead represent management’s expectations, estimates and projections regarding future events or circumstances. Such forward-looking statements are qualified in their entirety by the inherent risks, uncertainties and changes in circumstances surrounding future expectations which are difficult to predict and many of which are beyond the control of the Company. Forward-looking statements are necessarily based on a number of estimates and assumptions that, while considered reasonable by management of the Company as of the date of this press release, are inherently subject to significant business, economic and competitive uncertainties and contingencies and may prove to be incorrect. Material factors and assumptions used to develop the forward-looking statements, and material risk factors that could cause actual results to differ materially from the forward-looking statements, include but are not limited to, the timing and availability of the pediatric formats of Blexten from the Company’s suppliers to support commercial launch, other unanticipated delays in the commercial launch, the potential impact of COVID-19 on the Company’s operations, business and financial results and other factors, many of which are beyond the control of the Company. Additional factors that could cause the Company’s actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the risk factors included in the Company’s most recent Annual Information Form dated March 5, 2021 under the heading “Risks Factors”, and as described from time to time in the reports and disclosure documents filed by the Company with Canadian securities regulatory agencies and commissions. These and other factors should be considered carefully and readers should not place undue reliance on the Company’s forward-looking statements. Forward-looking statements should not be read as guarantees of future performance or results and will not necessarily be accurate indications of whether or not the times at or by which such performance or results will be achieved.

All forward-looking statements are based only on information currently available to the Company and are made as of the date of this press release. Except as expressly required by applicable Canadian securities law, the Company assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements in this press release are qualified by these cautionary statements.