Altamira Therapeutics Reports Additional Significant Efficacy Outcomes from Bentrio Clinical Trial in Seasonal Allergic Rhinitis

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HAMILTON, BERMUDA , Sept. 14, 2023 (GLOBE NEWSWIRE) --

- **Fresh data from randomized controlled NASAR clinical trial further demonstrate efficacy and tolerability of Bentrio® nasal spray in treatment of seasonal allergic rhinitis**
- **Study meets both primary and secondary efficacy endpoints of improvement in reflective and instantaneous Total Nasal Symptom Scores (p = 0.013 and 0.039)**
- **Corroborated by statistically significant improvement in health-related quality of life secondary efficacy endpoint (p < 0.001)**
- **Efficacy demonstrated from first day of 2-week treatment period on and across allergy symptoms and functional problems**
- **Bentrio treatment associated with reduced need for relief medication**

Altamira Therapeutics Ltd. (Nasdaq:CYTO), a company dedicated to developing therapeutics that address important unmet medical needs, today announced further positive and statistically significant efficacy data from the randomized controlled NASAR clinical trial, which evaluated their Bentrio nasal spray in seasonal allergic rhinitis (SAR). Bentrio nasal spray is formulated as a drug-free and preservative-free gel emulsion designed to help protect against airborne allergens such as pollen or house dust mites.

The NASAR trial enrolled 100 SAR patients in Australia who were randomized at a 1:1 ratio to receive either Bentrio or saline nasal spray, the current standard of care in drug-free SAR management. Study participants self-administered the treatment for two weeks three times per day, or as needed. For eligibility, patients had to have a reflective Total Nasal Symptom Score (rTNSS) of at least 5 points (out of 12), referring to the worst level of nasal congestion, sneezing, nasal itching, and rhinorrhea (runny nose) over the past 24 hours, during a one-week treatment-free run-in period. At baseline, patients recorded on average 6.9 points on the rTNSS scale, which is considered a moderate level.

As previously reported, the NASAR trial met its primary efficacy endpoint, with the Bentrio group showing a mean rTNSS over the treatment period of 5.0 points vs. 6.1 points for the saline spray group, resulting in a statistically significant difference of 1.1 points in the ANCOVA model[1] in favor of Bentrio (LSmeans; p = 0.013; 95% confidence interval -2.0 to -0.2). The reduction in nasal symptoms conferred by Bentrio was 2.4 times larger than with saline nasal spray and clinically relevant. The change in mean rTNSS over two weeks is generally accepted as a primary efficacy endpoint for SAR trials and also recommended by the FDA.

Additional data, which have become subsequently available from the NASAR trial, confirm and reinforce the body of evidence demonstrating Bentrio's efficacy in SAR management. The mean instantaneous TNSS (iTNSS), which measures nasal symptoms 'at the moment' and served as a secondary efficacy endpoint, was 4.4 points and 4.8 points at baseline. At the end of the treatment period, it reached 2.9 points in the Bentrio group vs. 3.7 points in the placebo group. Like for the TNSS, the difference of 0.8 points in the ANCOVA model was significantly larger for the Bentrio group (LSmeans; p = 0.039; 95% confidence interval -1.6 to -0.04). The treatment effect in favor of Bentrio became apparent from the first day of the two-week treatment period and was observed across the four nasal symptoms covered by the TNSS. It was particularly pronounced in patients with moderate to severe symptom levels.

Importantly, the alleviation of symptoms was associated with an improvement in health-related quality of life, as measured by the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ). The RQLQ has been designed to collect information on functional problems caused by allergic rhinitis. At baseline, the mean total RQLQ score was 3.0 points in the Bentrio group and 2.8 points in the saline spray group and decreased to 1.7 points and 2.4 points, respectively, by Day 14. The difference in improvement of 0.7 points in favor of Bentrio was statistically significant in the ANCOVA model (LSmeans; p < 0.001; 95% confidence interval -1.1 to -0.31) and clinically relevant. The improvement in the Bentrio group was significantly superior for each of the 8 RQLQ items, including nasal symptoms, eye symptoms, non-nose/eye symptoms, activity limitations, sleep problems, practical problems and emotional function.

Further, the read-out from the NASAR trial suggest that Bentrio helps reduce the need for relief medication (cetirizine nasal spray). Whereas a similar share of patients required relief medication during the treatment-free run-in period, more participants in the Bentrio group (11 out of 16; 68.7%) could abstain from relief medication during the treatment period, but only 4 out of 15 (26.6%) in the saline spray group. Within the overall group of patients, 20.8% of Bentrio treated patients required relief medication during treatment vs. 31.9% in the saline spray group.

As previously announced, 73.5% of Bentrio-treated study participants rated tolerability of the treatment as either good or very good vs. 85.5% of saline-treated participants. Among the latter, 10.4% reported tolerability as poor vs. only 6.1% in the Bentrio group. Adverse events were relatively rare (reported for 42.9 vs. 32.7%), mostly of mild severity and in the majority considered unrelated.

"The further read-out from the NASAR trial has provided a wealth of additional data, which apart from confirming the good safety and tolerability of Bentrio, provide strong evidence for its significant protective effects," commented Thomas Meyer, Altamira Therapeutics' founder, Chairman, and CEO. "We are particularly thrilled about the highly significant improvement in health-related quality of life, which does matter a lot to patients and complements nicely the significant reduction in nasal symptoms. In addition, we are very encouraged to see that Bentrio helps to manage not only mild allergy symptoms, but also more severe ones, and appears to reduce the need for the use of drug-based relief treatments."

“With efficacy data that is approaching that of medicated nasal sprays, yet a safety and tolerability profile that is similarly favorable as for seawater nasal sprays, we believe that Bentrio provides an attractive treatment option for patients who have to deal with the daily burden and discomfort associated with allergic rhinitis. Through partnering with strong and dedicated marketing and distribution partners, we intend to make Bentrio available to a growing number of patients world-wide and help them to improve their condition and well-being.”

About Bentrio

Bentrio is an OTC drug-free nasal spray for personal protection against airborne allergens and, where approved, against airborne viruses. Upon application into the nose, Bentrio forms a protective gel layer on the nasal mucosa. This thin film is designed to prevent the contact of allergens (or virus particles) with cells; in addition, the composition serves to bind such particles and help with their discharge. Together, this is designed to promote alleviation of allergic symptoms (or mitigate upper respiratory tract viral infections). For more info, visit: https://altamiratherapeutics.com/legacy-programs/bentrio

About Altamira Therapeutics

Altamira (Nasdaq: CYTO) is dedicated to developing RNA-based therapeutics for extrahepatic targets (OligoPhore / SemaPhore delivery platforms). The Company currently has two flagship siRNA programs in preclinical development beyond in vivo proof of concept: AM-401 for KRAS driven cancer and AM-411 for rheumatoid arthritis. The versatile delivery platform is also suited for mRNA and other types of RNA therapeutics and is planned to be leveraged via out-licensing to pharma or biotech companies. In addition, Altamira is in the process of divesting and/or out-licensing its legacy assets in allergology and viral infection (Bentrio OTC nasal spray; commercial) and inner ear therapeutics (AM-125 nasal spray for vertigo; post Phase 2; Keyzilen® and Sonsuvi® for tinnitus and hearing loss; Phase 3). Founded in 2003, Altamira is headquartered in Hamilton, Bermuda, with its main operations in Basel, Switzerland. For more information, visit: https://altamiratherapeutics.com

Forward-Looking Statements

This press release may contain statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical facts and may include statements that address future operating, financial or business performance or Altamira Therapeutics' strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may", "might", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "projects", "potential", "outlook" or "continue", or the negative of these terms or other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include, but are not limited to, the success of the continued commercialization of Bentrio and success of strategic transactions, including licensing or partnering, with respect to Bentrio or any other legacy assets, Altamira Therapeutics' need for and ability to raise substantial additional funding to continue the development of its product candidates, the timing and conduct of clinical trials of Altamira Therapeutics' product candidates, the clinical utility of Altamira Therapeutics' product candidates, the timing or likelihood of regulatory filings and approvals, Altamira Therapeutics' intellectual property position and Altamira Therapeutics' financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to Altamira Therapeutics' capital structure, including future securities offerings. These risks and uncertainties also include, but are not limited to, those described under the caption "Risk Factors" in Altamira Therapeutics' Annual Report on Form 20-F for the year ended December 31, 2022, and in Altamira Therapeutics' other filings with the SEC, which are available free of charge on the Securities Exchange Commission's website at: www.sec.gov. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated. All forward-looking statements and all subsequent written and oral forward-looking statements attributable to Altamira Therapeutics or to persons acting on behalf of Altamira Therapeutics are expressly qualified in their entirety by reference to these risks and uncertainties. You should not place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date they are made, and Altamira Therapeutics does not undertake any obligation to update them in light of new information, future developments or otherwise, except as may be required under applicable law.

[1] Using baseline rTNSS score, average use of relief medication (cetirizine nasal spray) and treatment group as covariates.

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