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Â Novartis AG (Name of Registrant) Â Lichtstrasse 35 4056 Basel Switzerland (Address of Principal Executive Offices) Â

Â Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F: Form 20-F:Â ~ Â Form 40-F:Â ~ Â Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.Â Yes:Â ~ Â No:Â ~ Â

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Â MEDIA & INVESTOR RELEASE Â

Â Novartis intrathecal onasemnogene abeparvovec Phase III study meets primary endpoint in children and young adults with SMA

Â Ad hoc announcement pursuant to Art. 53 LR Â

Â The Phase III STEER study met its primary endpoint showing an increase from baseline in HFMSE total score in patients with SMA treated with intrathecal onasemnogene abeparvovec (OAV101 IT) Â

Â OAV101 IT is the first investigational gene therapy to provide clinical benefit in treatment-naïve patients with SMA aged two and older with a positive risk benefit profile Â

Â Novartis plans to share results with regulatory agencies in 2025 with the aim to make OAV101 IT available to help patients with SMA in need Â

Â Basel, December 30, 2024 Â

Novartis today announced positive topline results from the Phase III STEER study. This pivotal study assessed the efficacy and safety of investigational intrathecal onasemnogene abeparvovec (OAV101 IT) in treatment-naïve patients with spinal muscular atrophy (SMA) Type 2, aged two to less than 18 years who are able to sit but have never walked independently.1 Efficacy and safety results for OAV101 IT were compared against a sham control, a procedure designed to mimic the administration of an investigational drug, without delivering any active treatment. The STEER study met its primary endpoint showing an increase from baseline across the study population in total Hammersmith Functional Motor Scale - Expanded (HFMSE) scores. HFMSE is a gold standard for SMA-specific assessment of motor ability and disease progression.2,3,4,5,6 The increase was observed in patients treated with OAV101 IT compared to sham controls indicating better motor function in patients with SMA. The safety profile of OAV101 IT was favorable. The overall adverse events and serious adverse events were similar between arms.Â The most common adverse events were upper respiratory tract infection, pyrexia and vomiting. Novartis plans to share results with regulatory agencies in 2025, including the US Food and Drug Administration (FDA), with the aim to make OAV101 IT available to help patients with SMA in need. Data will be presented at an upcoming medical meeting in 2025. Â

Many patients with SMA currently rely on chronic treatments to manage their disease. These positive topline results from the STEER trial underscore the efficacy, safety and tolerability of OAV101 IT in patients with SMA aged two and above,Â said Shreeram Aradhye, M.D., President, Development and Chief Medical Officer, Novartis. Â

The totality of evidence clearly supports a positive risk benefit profile of OAV101 which is expected to support registration covering a broad range of SMA patients. We remain committed to leading innovation in SMA treatment through our one-time gene therapies, uniquely designed to replace the function of the missing or defective SMN1 gene.Â

Maintaining motor function is a key goal for many older patients with SMA.Â This may allow them the capacity to continue to propel their electric wheelchair, feed themselves with intact hand to mouth function, and perform other activities of daily living as independently as possibleÂ said Crystal Proud, M.D., Pediatric Neurologist and a Principal Investigator at Children's Hospital of the King's Daughters. OAV101 IT administration has not only been demonstrated to maintain motor function, but also increased it in indicating the impact a one-time therapy could have.Â

Results from STEER build on the Phase I/II open-label STRONG study which showed that treatment with OAV101 IT led to a clinically meaningful increase in HFMSE scores in one year,7 and a clinically meaningful response in patients aged two to five years with SMA Type 2, who were able to sit but had never walked independently.7 The results from the Phase III STEER study add to the clinical data and emerging real-world evidence for the use of one-time gene therapy to treat SMA. STEER Study STEER is a Phase III randomized, double-blind, sham-controlled study to evaluate the clinical efficacy, safety, and tolerability of a one-time dose of intrathecal onasemnogene abeparvovec (OAV101 IT) in treatment-naïve patients with SMA Type 2, aged two to less than 18 years who were able to sit, but had never walked independently.1 The therapeutic effect of OAV101 IT was evaluated using the Hammersmith Functional Motor Scale - Expanded (HFMSE) scores.1 This is a validated assessment tool specifically designed to evaluate motor abilities and disease progression in patients with SMA. Secondary objectives included evaluating safety and efficacy of OAV101 IT using the Revised Upper Limb Module (RULM) scale.1 More than 100 patients were randomized to receive OAV101 by IT injection or to receive a sham procedure.1 At the end of the 52-week period, all eligible patients who received the sham procedure received OAV101 IT and all eligible patients who received OAV101 IT received the sham procedure.1 About OAV101 IT Intrathecal onasemnogene abeparvovec (OAV101 IT) is an investigational, one-time gene therapy for patients with spinal muscular atrophy (SMA). OAV101 IT was evaluated in three clinical studies, including the Phase III STEER study, Phase I/II STRONG study and the Phase IIb STRENGTH study.1,7,8, 9 The STEER study was a randomized, double-blind, sham-controlled study to evaluate the clinical efficacy, safety, and tolerability of OAV101 IT in treatment-naïve patients with SMA Type 2, aged two to less than 18 years who were able to sit, but had never walked independently.1 The STRENGTH study was an open-label, single arm, multi-center study evaluating the safety, tolerability and efficacy of OAV101 IT in patients with SMA who had discontinued treatment with nusinersen or risdiplam.9 The STRONG study was an open-label, dose ranging study evaluating the safety and efficacy of OAV101 IT in patients with SMA with 3 copies of SMN2 aged 6 months to less than 60 months. The OAV101 IT clinical development program was studied in a broad population of approximately 170 patients with SMA and follow-up was conducted for up to 6.4 years.10 Novartis has an exclusive, worldwide license with Nationwide Children's Hospital to both the intravenous and intrathecal delivery of adeno-associated virus 9 (AAV9) gene therapy for the treatment of all types of SMA; an exclusive, worldwide license from REGENXBIO for any recombinant AAV vector in its intellectual property portfolio for the in vivo gene therapy treatment of SMA in humans; an exclusive, worldwide licensing agreement with G&A for in vivo delivery of AAV9 vector into the central nervous system for the treatment of SMA. Â

About Spinal Muscular Atrophy Spinal muscular atrophy (SMA) is a rare, genetic neuromuscular disease caused by a lack of a functional SMN1 gene, resulting in the irreversible loss of motor neurons, affecting muscle functions, including breathing, swallowing

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M!8%+BI;BUFM9C',C(XZ@BF5X4KIV9]&I*2NA,4N*7%+638Q,4N*7%+BH;)N) MBEQ2XI<5#8KB
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)Z+9'SO16OKWAC6/#-V;?5;*2!OX7ZH_P#N MMT-9%>]&2DKH\5IK<****8@HHHH **** "BBB@
JQ8V>TU"TEMKA,J2+@__ %ZI MU]DZYX;TGQ)9FUU6RCN\$ _A8C#)[JW45XCXN^".HZ<9+KP_(U);#G[._ \$JCV[M-
7JT<;">DM&B,?PSX:U#Q5K,6FZ?'EF.9 M)"/EC7NS5]8^&] L_#A6VEV2XCA7YF(Y=N['ZU6*>\$=+'Z8+/3HOF;!EG M;
[K>I PK?KQ,3B'5=EL=U*GR;[BT445R&P4444 % % % % !1110 4444 % % % % M
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.P&*EHHKM45%61QMM[BT4450!1110 4444 % % % % !1110!A:]X1T' MQ)\$1JNFPSMC EQM3K_P
M+MM_/KCI^E=LBjB!\$4*j\ 8 HHKEE4E-^\[/FJBH[#Z***104444 ?_9 end