Servier Presents Long-Term INDIGO Analyses Demonstrating Sustained Clinical Benefit of VORANIGO® (vorasidenib) in IDH-Mutant Glioma Across Subgroups at SNO 2026

- Extended Phase 3 INDIGO follow-up results, including data from patients who crossed over to VORANIGO® (vorasidenib) from placebo, were presented as an oral presentation on November 14
- Exploratory INDIGO analysis providing insight into VORANIGO's impact on seizure control and quality of life were presented as an oral presentation on November 15

BOSTON, Nov. 17, 2026 /PRNewswire/ -- Servier announced extended follow-up results and subgroup analyses from the Phase 3 INDIGO trial evaluating VORANIGO® (vorasidenib) in mutant isocitrate dehydrogenase 1 or 2 (IDH1/2) glioma who received treatment following surgery as their primary therapy were presented at the 31st Society for Neuro-Oncology (SNO) Annual Meeting in Philadelphia. These analyses provide longer-term insights into VORANIGO's clinical benefit across evaluated subgroups. Alongside these data, an exploratory analysis of seizure activity and quality of life among INDIGO patients was also presented.

The updated Phase 3 INDIGO results include analyses of 144 of 163 patients randomized to placebo who crossed over to VORANIGO from placebo by the January 17, 2025 data cutoff, along with analyses by histology in oligodendroglioma and astrocytoma. These results build on findings previously reported at ASCO, which demonstrated continued benefit in progression-free survival (PFS) at a median follow-up time of 41.6 months.

"The results from the INDIGO analyses presented at SNO reinforce the clinical benefit of VORANIGO in patients with Grade 2 IDH-mutant glioma, with the crossover patient population data demonstrating consistent results," said Islam Hassan, M.D., MSc., Global Head of Development, Neuro-Oncology at Servier. "Together with the data on VORANIGO's impact on quality of life, these findings strengthen our understanding of the impact of VORANIGO over time and underscore its important role in glioma care."

Efficacy data and subgroup analyses after extended follow-up with vorasidenib in INDIGO – a global, randomized, placebo-controlled, double-blinded, Phase 3 trial in grade 2 mutant isocitrate dehydrogenase 1/2 (mIDH1/2) glioma — November 14, 5:00–5:07 p.m. EST

The latest results from this analysis were presented by Timothy F. Cloughesy, M.D., David Geffen School of Medicine, Department of Neurology, University of California, Los Angeles, an investigator for the INDIGO trial. These data showed clinical benefit among patients who crossed over from placebo and across subgroups defined by histologic subtype. Key findings include:

- Among patients who crossed over to VORANIGO, median PFS per investigator was 37.2 months overall (95% CI, 33.4-not estimable [NE]). Among patients with astrocytoma who crossed over, median PFS by investigator was 37.2 months (95% CI, 25.6-NE) and in patients with oligodendroglioma who crossed over, median PFS by investigator was not reached (95% CI, 24.6-NE). Median PFS per investigator was 33.4 months (95% CI, 24.6 months-NE) for patients with progressive disease (PD) at crossover and was NE for patients with no PD at crossover.
- In a post-hoc analysis of patients who crossed over to VORANIGO from placebo, VORANIGO reversed average tumor growth; tumor volume increased on average by 16.1% per six months before crossover and decreased on average by 2.9% per six months after crossover. The shift from growth to shrinkage was observed in both oligodendroglioma and astrocytoma subgroups.
- The substantial increase in objective response rate (ORR) by blinded independent review committee (BIRC) over time for the overall population (from 10.7% [95% CI, 6.5%–16.4%] in September 2022 to 20.8% [95% CI, 15.0%–27.8%] in January 2025) is reflected in patients with astrocytoma (increase from 7.5% [95% CI, 2.8%–15.6%] to 17.5% [95% CI, 9.9%–27.6%]) as well as those with oligodendroglioma (increased from

13.6% [95% CI, 17.2 %-22.6%] to 23.9% [95%, CI, 15.4%–34.1%]).

- The safety profile remained consistent with previous data cutoffs with no new safety signals identified during extended follow-up or in crossover patients. Grade ≥3 treatment-emergent adverse events (TEAEs) occurred in 31.7% of patients randomized to VORANIGO and 20.1% of those crossed over from placebo. The most commonly reported Grade ≥3 TEAEs were increased alanine aminotransferase (10.8% and 7.6%), increased aspartate aminotransferase (4.8% and 3.5%), seizure (4.8% and 4.2%) and increased gamma-glutamyltransferase (GGT; 3% and 0.7%). There were no treatment-related deaths in either group, and TEAEs leading to discontinuation were uncommon among patients randomized to VORANIGO (4.8%) and those who crossed over from placebo (2.1%).

"Longer follow-up from INDIGO continues to demonstrate the durable clinical benefit of IDH-inhibition for patients with Grade 2 IDH-mutant glioma across patient subgroups," said Dr. Timothy Cloughesy. "These findings also show promising results in patients who crossed over from placebo, including those whose disease had already progressed, providing further insight into the potential role of IDH inhibition to help manage disease over time."

Impact of vorasidenib vs placebo on seizure rates and quality of life: exploratory analysis from Phase 3 INDIGO study — November 15, 11:07–11:14 a.m. EST

An exploratory analysis presented as an encore by Wolfgang Wick, M.D., Universitätsklinikum Heidelberg & German Cancer Research Center, examined seizure activity and quality of life in INDIGO participants who experienced at least one seizure in the baseline and/or on-treatment periods. At the January 17, 2025, data cutoff:

- In the overall population of patients treated with VORANIGO, the proportion of patients with on-treatment seizures remained stable from March 2023 to January 2025 (98.1% vs 98.2%). Moreover, the seizure rate with VORANIGO decreased from 18.2 (95% CI, 8.4–39.5) to 15.9 (95% CI, 9.1–27.1) seizures per person-year between March 2023 and January 2025.
    - The rate ratio versus placebo improved from 0.36 (95% CI, 0.14–0.89; P=0.0263) to 0.28 (95% CI, 0.14–0.55; P=0.0002), supporting a sustained treatment effect with longer follow-up.
- VORANIGO was associated with long-term stabilization of seizure frequency overall and across both oligodendroglioma and astrocytoma. Patients with oligodendroglioma treated with VORANIGO showed a trend towards low, stable seizure counts and patients with astrocytoma experienced low seizure counts regardless of treatment.
- VORANIGO was associated with sustained preservation of quality of life, with exploratory analyses in patients with ≥1 seizure, showing a lower risk of worsening versus placebo on the Functional Assessment of Cancer Therapy–Brain (FACT-Br) scale (HR=0.38; 95% CI, 0.15–1.00) and its brain cancer subscale (HR=0.32; 95% CI, 0.11–0.91).

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Servier takes a One Innovation Engine approach to R&D and is actively seeking alliances, partnerships and acquisitions at various stages of the portfolio.

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About Glioma[1]
Gliomas are tumors that arise from glial or precursor cells within the central nervous system (CNS). The 2021 World Health

Organization (WHO) classification recognizes four general groups of gliomas, one of which is adult-type diffuse gliomas. These diffuse gliomas are the most common primary malignant brain tumors in adults. The pathogenesis and prognosis of these tumors are tightly linked to mutations (or lack thereof) in the metabolic enzyme isocitrate dehydrogenase (IDH), and molecular testing is required for proper diagnosis. As of 2021, adult-type diffuse gliomas are sub-divided into only three categories:

- Astrocytoma, IDH-mutant (CNS WHO grades 2-4)
- Oligodendroglioma, IDH-mutant and 1p/19q-codeleted (CNS WHO grades 2-3)
- Glioblastoma, IDH-wildtype (CNS WHO grade 4)

VORANIGO IMPORTANT SAFETY INFORMATION

What is VORANIGO?

VORANIGO (40 mg tablets) is a prescription medicine used to treat adults and children 12 years of age and older with certain types of Grade 2 brain tumors called astrocytoma or oligodendroglioma with an isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, following surgery. Your healthcare provider will perform a test to make sure that VORANIGO is right for you. It is not known if VORANIGO is safe and effective in children under 12 years of age.

What are the possible side effects of VORANIGO?

VORANIGO may cause serious side effects, including:

- **Liver problems.** Changes in liver function blood tests may happen during treatment with VORANIGO and can be serious. Your healthcare provider will do blood tests to check your liver function before and during treatment with VORANIGO. Tell your healthcare provider right away if you develop any of the following signs and symptoms of liver problems:

- yellowing of your skin or the white part of your eyes (jaundice)
- dark tea-colored urine
- loss of appetite
- pain on the upper right side of your stomach area
- feeling very tired or weak

The most common side effects of VORANIGO include:

- increased liver enzyme levels in the blood
- lack of energy, tiredness
- headache
- COVID-19
- muscle aches or stiffness
- diarrhea
- nausea
- seizure

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with VORANIGO if you have certain side effects.

VORANIGO may affect fertility in females and males, which may affect the ability to have children. Talk to your healthcare provider if this is a concern for you.
These are not all of the possible side effects of VORANIGO.

Before taking VORANIGO, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have kidney problems or are on dialysis
- smoke tobacco
- are pregnant or plan to become pregnant. VORANIGO can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with VORANIGO
- You should use effective nonhormonal birth control during treatment with VORANIGO and for 3 months after the last dose. VORANIGO may affect how hormonal contraceptives (birth control) work and cause them to not work well. Talk to your healthcare provider about birth control methods that may be right for you during treatment with VORANIGO
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with VORANIGO

Males with female partners who are able to become pregnant:

- You should use effective birth control during treatment with VORANIGO and for 3 months after the last dose
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she may be pregnant during your treatment with VORANIGO

Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if VORANIGO passes into breast milk. **Do not** breastfeed during treatment with VORANIGO and for 2 months after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VORANIGO may affect the way other medicines work, and other medicines may affect how VORANIGO works.

Please click here for full prescribing information.

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