Soligenix Investor Relations

Soligenix Details Recent Progress and Upcoming Milestones

PRINCETON, N.J., Feb. 12, 2026 /PRNewswire/ -- Soligenix, Inc. (Nasdaq: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need, today issued an update letter from its President and Chief Executive Officer, Dr. Christopher J. Schaber. The content of this letter is provided below.

Dear Friends and Shareholders,

I would like to start by thanking you for your continued support, and by wishing you and your families a Happy New Year. With 2026 being an important year for us, we remain energized by the promise of our late-stage rare disease pipeline as we continue to evaluate potential strategic options, including, but not limited to, partnership and merger and acquisition opportunities. The previously publicly disclosed upcoming key clinical events and milestones are summarized below.

- Top-line results from the actively enrolling 80 patient confirmatory Phase 3 FLASH**2** (Fluorescent Light And Synthetic Hypericin **2**) clinical trial for HyBryte™ (SGX301 or synthetic hypericin) in the treatment of early-stage cutaneous T-cell lymphoma (CTCL) are expected in the second half of 2026, with an interim analysis fast approaching in 2Q. Patient enrollment continues to progress nicely with 66 patients enrolled in the study as of February 10th. Importantly, the overall blinded aggregate response rate remains consistent with what was reported in November and higher than the estimated overall response rate used to design the study, increasing our confidence in the interim analysis and final study results. Just to remind you, this second Phase 3 trial (FLASH**2**) essentially replicates the first successful Phase 3 (FLASH) study, with the exception of shifting the primary endpoint assessment from 6 weeks in FLASH to 18 weeks in FLASH**2**, in keeping with findings in both the FLASH study and other recent supportive studies that have all shown that the longer we treat with HyBryte™, the better it works.

- A clinical update was provided for the ongoing open-label, investigator-initiated study (IIS) sponsored by Ellen Kim, MD, Director, Penn Cutaneous Lymphoma Program, Vice Chair of Clinical Operations, Dermatology Department, and Professor of Dermatology at the Hospital of the University of Pennsylvania who was a leading enroller in the Phase 3 FLASH study and is the Principal Investigator for the confirmatory Phase 3 FLASH**2** study for the treatment of early-stage CTCL. The IIS evaluated extended HyBryte™ (synthetic hypericin) treatment for up to 54 weeks in patients with early-stage CTCL, with a similar design to that of the active HyBryte™ arm in FLASH**2**. Following 18 weeks of continuous "real world" treatment, 75% of patients achieved "Treatment Success," with three of the eight evaluable patients achieving a complete response over the course of the study. These results reinforce HyBryte™'s potential as a safe and fast-acting therapy for this chronic and underserved cancer and may explain, in part, the higher aggregate blinded response rate seen in FLASH**2**.

- We continue to work with our lead investigators in CTCL, including pursuing publications to enhance both medical and scientific awareness of HyBryte™. We anticipate additional publications around HyBryte™ in the first half of the year.

- Top-line results from the Phase 2a proof of concept clinical trial in Behçet's Disease (BD) with SGX945 (dusquetide) were reported in July and achieved the study objective of demonstrating biological efficacy. The Phase 2a study was an open-label study designed to be highly comparable (e.g., study endpoints, inclusion-exclusion criteria) to the published Phase 3 study of apremilast (Otezla®) used to support marketing approval for oral ulcers in BD. SGX945 outcomes were compared to both the apremilast and placebo arms in this Phase 3 study. Over 4 weeks of treatment, the area under the curve (AUC; a composite measurement of both peak number of oral ulcers and the time to resolution of the oral ulcers), average number of oral ulcers, and improvements in oral pain for SGX945 were similar to outcomes obtained in the apremilast study. Notably, outcomes in weeks 5 through 8 continued to show similar outcomes to the apremilast study, even though apremilast treatment was continued through this period whereas SGX945 treatment was stopped at Week 4, per study design. These results were published in Rheumatology (Oxford) in December. With these results, we intend to embark on a reformulation of SGX945 to enable home-based treatment and look forward to interacting with the health authorities in designing a follow-on placebo-controlled Phase 2b study in 2026.

- Top-line results were reported in December for the last cohort of four patients in the Phase 2a clinical trial in mild-to-moderate psoriasis with SGX302 (synthetic hypericin), where SGX302 gel therapy was well tolerated by all patients with no drug related adverse events identified. On average over the three evaluable patients (one patient discontinued for personal reasons), there were improvements in the Investigator Global Assessment (IGA), the Psoriasis Activity and Severity Index (PASI), the simplified psoriasis index, the dermatology life quality index and the Skindex-29 questionnaire. One patient achieved a disease status of "Almost Clear" using the IGA, which is considered a standard clinical measure for treatment success in psoriasis, with a substantial improvement in their PASI score, exceeding 50%. In totality, the initial exploratory phase of the study has confirmed that SGX302 improves psoriasis lesions, consistent with the general success of photodynamic therapies in psoriasis, and is well tolerated, potentially providing a non-carcinogenic, non-mutagenic treatment for the thicker lesions found in psoriasis. With the completion of this pilot study, the table has been

set for a more detailed evaluation in this large underserved market.

Additionally, we continue to follow through on our financing strategies, and have sufficient capital and cash runway to meet our goals through 2026. We expect peak annual net sales of HyBryte™ in the U.S. to exceed $90 million, with the total addressable worldwide CTCL market estimated at greater than $250 million annually. Preliminary analysis of the total addressable worldwide psoriasis market opportunity with SGX302, which uses the same active ingredient as HyBryte™, is significant and estimated to exceed $1 billion annually. SGX945 in BD is another meaningful worldwide market opportunity estimated at approximately $200 million annually. Overall, we are excited about our near-term and future upcoming catalytic milestones across our rare disease pipeline, with the potential for significant commercial returns of ~$2B in global annual sales.

With approximately $10.5 million in cash reported in our Form 10-Q for the quarter ended September 30, 2025, not including approximately $500 thousand in non-dilutive funding received through New Jersey's net operating loss (NOL) sales program, we remain focused on advancing our development programs in our Specialized BioTherapeutics rare disease business segment, most notably, completion of our confirmatory Phase 3 HyBryte™ clinical trial, *where we currently anticipate achieving multiple important and potentially transformational milestones through 2026*. We also continue to evaluate strategic options before us to better position the company for growth and success.

We remain steadfast in our plans for partnership in the ex-U.S. markets and continue to pursue discussions with potential partners with similar reputation and expertise in this therapeutic area, as we advance towards successful completion of the FLASH**2** confirmatory trial in order to aggressively pursue HyBryte™ marketing authorizations worldwide. Given HyBryte™'s clinical success in CTCL, we also are evaluating other potential cutaneous indications that might similarly benefit from the use of our first-in-class synthetic hypericin.

In closing, thank you again for your interest and your ongoing support of Soligenix. Looking ahead, 2026 has the potential to be an exciting time for the Company, as we further advance our development programs towards commercialization. Best wishes!

Dr. Christopher J. Schaber
President and Chief Executive Officer
Soligenix, Inc.
February 12, 2026

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that reflect Soligenix's current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations, clinical trial enrollment. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "hopes," "intends," "plans," "expects," "goal," "may," "suggest," "will," "potential," or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual events or results in future periods to differ materially from what is expressed in, or implied by, these statements. Soligenix cannot assure you that it will be able to successfully develop, achieve regulatory approval for or commercialize products based on its technologies, particularly in light of the significant uncertainty inherent in developing therapeutics and vaccines against bioterror threats, conducting preclinical and clinical trials of therapeutics and vaccines, obtaining regulatory approvals and manufacturing therapeutics and vaccines, that product development and commercialization efforts will not be reduced or discontinued due to difficulties or delays in clinical trials or due to lack of progress or positive results from research and development efforts, that it will be able to successfully obtain any further funding to support product development and commercialization efforts, including grants and awards, maintain its existing grants which are subject to performance requirements, enter into any biodefense procurement contracts with the U.S. Government or other countries, that it will be able to compete with larger and better financed competitors in the biotechnology industry, that changes in health care practice, third party reimbursement limitations and Federal and/or state health care reform initiatives will not negatively affect its business, or that the U.S. Congress may not pass any legislation that would provide additional funding for the Project BioShield program. In addition, there can be no assurance as to the timing or success of any of its clinical/preclinical trials. Despite the statistically significant result achieved in the first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma or any other studies (including the open-label, investigator-initiated study) and the overall blinded aggregate response rate observed in the second HyBryte™ (SGX301) Phase 3 clinical trial, there can be no assurance that the second HyBryte™ (SGX301) Phase 3 clinical trial will be successful or that a marketing authorization from the FDA or EMA will be granted. Additionally, although the EMA has agreed to the key design components of the second HyBryte™ (SGX301) Phase 3 clinical trial, no assurance can be given that the Company will be able to modify the development path to adequately address the FDA's concerns or that the FDA will not require a longer duration comparative study. Notwithstanding the result in the first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 2a clinical trial of SGX302 for the treatment of psoriasis, there can be no assurance as to the timing or success of the clinical trials of SGX302 for the treatment of psoriasis. Additionally, despite the biologic activity observed in aphthous ulcers induced by chemotherapy and radiation, there can be no assurance as to the timing or success of the clinical trials of SGX945 for the treatment of Behçet's Disease. Further, there can be no assurance that RiVax® will qualify for a biodefense Priority Review Voucher (PRV) or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. Also, no assurance can be provided that the Company will receive or continue to receive non-

dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission (the "SEC"), including, but not limited to, Soligenix's reports on Forms 10-Q and 10-K. Unless required by law, Soligenix assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

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For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200 | www.soligenix.com, Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540
