September 8, 2026

Inhibitor Therapeutics Highlights Key Developments and Reminds Stockholders of September 15 Annual Meeting

TAMPA, Fla., Sept. 08, 2026 (GLOBE NEWSWIRE) -- Inhibitor Therapeutics, Inc. (OTCQB: INTI) ("Inhibitor" or the "Company") today highlighted several important developments disclosed in its Quarterly Report on Form 10-Q filed August 14, 2026, and encouraged stockholders and other interested parties to review the filing for a more complete discussion of the Company's progress.

Recent progress includes a revised regulatory strategy for itraconazole in Basal Cell Carcinoma Nevus Syndrome ("BCCNS" or "Gorlin Syndrome"), descriptive characterization of prospectively collected measurements from the completed Phase IIb HP2001 study, continued FDA engagement, development of a proposed commercial formulation, a new provisional patent filing, outside scientific support and a favorable Delaware Court of Chancery judgment.

INTI is proposing surgically eligible basal cell carcinomas as the primary efficacy endpoint for the program. The endpoint focuses on tumors that have reached a size at which surgical removal would ordinarily be warranted. It was used in the randomized, placebo-controlled Tang study of vismodegib in Gorlin Syndrome[1], where treatment reduced both the development of new surgically eligible tumors and the number of performed patient surgeries. Separately, vismodegib was approved by FDA for advanced basal cell carcinoma based on single-arm response data in an advanced-disease population. INTI believes these two distinct precedents provide important clinical and regulatory context for the Company's questions now before FDA.

Applying the same site-based surgical thresholds used in the Tang study to prospectively collected HP2001 lesion measurements identified 258 surgically eligible baseline tumors. A descriptive characterization of those tumors showed that 52.7% achieved an objective response, 87.2% were controlled, and the mean best reduction in longest diameter was 40.4%. HP2001 enrolled 38 patients and followed 477 target basal cell carcinomas in total. These descriptive readings characterize observed therapeutic activity in the small, operable tumors that drive the repeated surgical burden of Gorlin Syndrome.

Applying the same surgical thresholds to prospectively collected measurements of tumors arising during HP2001 identified 10 new surgically eligible tumors across seven patients during 37.77 patient-years of on-treatment exposure, corresponding to a descriptive rate of 0.265 per patient-year - well below one new surgically eligible tumor per patient-year. For context, the separate randomized Tang study reported approximately 2 new surgically eligible tumors per patient-year with vismodegib and approximately 29 per patient-year with placebo. The markedly low on-treatment rate observed in HP2001 is particularly notable in a lifelong disease characterized by the continual development of new BCCs and forms part of

the Company's request for FDA guidance on the use of the Tang placebo experience as an external control for the HP2001 new-lesion endpoint.

These findings align closely with outcomes identified as important by the Gorlin Syndrome patient community. In the Gorlin Syndrome Alliance Voice of the Patient report, 70% of respondents selected preventing BCCs from developing as one of their top three desired treatment outcomes, and 94% said that a preventive treatment reducing new basal cell carcinomas by 30% without challenging side effects would represent an improvement over current options[3]. Against that patient-defined benchmark, the descriptive HP2001 rate of 0.265 new surgically eligible BCCs per patient-year is an encouraging finding. The numerical separation between the HP2001 rate and the rates reported in Tang is considerably greater than the 30% threshold patients identified, although the cross-trial comparison is descriptive and is not an adjusted treatment-effect estimate. Taken together, the results support further evaluation of itraconazole as a potential preventive therapy aimed at reducing the development of new BCCs to surgical eligibility. The observation is also biologically plausible given itraconazole's demonstrated antitumor activity in human BCC and preferential distribution into cutaneous tissue[2].

The patient-defined prevention benchmark also emphasized the importance of avoiding challenging side effects, making tolerability and treatment persistence particularly relevant in a condition that may require long-term management. In HP2001, 13.2% of patients discontinued itraconazole because of adverse events over a median of approximately 7.0 months on treatment. In the randomized Tang Gorlin study, 27% of patients had discontinued vismodegib because of adverse events at a mean observation time of approximately 8 months, rising to 54% at the later study cutoff. Although these are separate studies rather than a head-to-head safety comparison, the observed itraconazole tolerability and treatment persistence align strongly with the treatment profile patients said they wanted: fewer new tumors together with a therapy suitable for sustained use.

Measure	HP2001 itraconazole	Tang vismodegib	Tang placebo
Mean reduction in existing surgically eligible tumors	40.4%	Approx. 65%	Approx. 11%
New surgically eligible BCCs per patient-year	0.265	Approx. 2	Approx. 29
Adverse-event-related discontinuation	13.2% (median approximately 7 months)	27% at approx. 8 months; 54% at later cutoff	—

Selected descriptive cross-trial context from INTI's Type C Meeting Information Package and Tang et al. (2012). Each figure describes its respective study; the comparison is not an adjusted between-study treatment-effect estimate.

1 Tang JY, Mackay-Wiggan JM, Aszterbaum M, et al. N Engl J Med. 2012;366(23):2180-2188. doi:10.1056/NEJMoa1113538.

2 Kim DJ et al. J Clin Oncol. 2014;32(8):745-751. doi:10.1200/JCO.2013.49.9525; Cauwenbergh G et al. J Am Acad Dermatol. 1988;18(2 Pt 1):263-268. doi:10.1016/S0190-9622(88)70037-7.

3 Gorlin Syndrome Alliance. Voice of the Patient Report: Living with Gorlin Syndrome. Externally Led Patient-Focused Drug Development Meeting, October 8, 2021; published 2022, p. 45.

On July 10, 2026, INTI submitted a meeting request and associated briefing package to FDA. The Company is seeking FDA guidance on the proposed surgically eligible tumor endpoint for the non-advanced Gorlin population, the use of the existing clinical evidence within a potential marketing application under Section 505(b)(2), and the path forward for the program. The briefing package specifically asks FDA to consider the HP2001 readings, whether expressed at the surgically eligible threshold or per lesion, as descriptive characterizations of prospectively collected measurements rather than inferential post-hoc tests of a treatment effect. FDA subsequently classified the meeting as Type C, elected to provide written responses and has stated a goal date by the end of September 2026.

The Company's regulatory position is also supported by outside scientific and clinical input, including a letter submitted to FDA from Professor D. Gareth Evans, an internationally recognized expert in inherited cancer-predisposition syndromes and Gorlin Syndrome, addressing the disease biology, the independent nature of the tumors and the clinical importance of reducing surgical burden.

Formulation work also advanced during the period. The completed ITZ101 pilot comparative-bioavailability study showed that the Company's 75 mg formulation produced systemic exposure most comparable to TOLSURA® 65 mg, with geometric mean ratios of 105.36% for AUC0-t and 102.19% for Cmax. Based on those results, the Company intends to advance an approximate 75 mg formulation.

On August 14, 2026, the Company filed a U.S. provisional patent application covering its novel oral itraconazole formulation, including its amorphous nano/microparticle composition and related pharmaceutical uses. The filing is intended to support formulation-specific and related-use intellectual-property protection extending beyond the February 2029 expiration of the licensed Johns Hopkins University patent. Itraconazole also has FDA Orphan Drug Designation for BCCNS, which may provide a separate period of U.S. regulatory exclusivity following approval for the designated indication, subject to applicable requirements.

The program also carries meaningful commercial potential. An internal illustrative model assumes an estimated U.S. BCCNS population of approximately 11,000 patients, approximately one-third market penetration and illustrative pricing of $4,000 to $5,000 per patient per month. Under those assumptions, approximately 3,700 treated patients would correspond to potential peak annual U.S. revenue of approximately $178 million to $222 million. The analysis is for internal strategic planning, is highly sensitive to its assumptions and is not Company financial guidance or a revenue forecast.

Separately, on August 3, 2026, the Delaware Court of Chancery entered a default judgment in favor of the Company against the institutional investor that failed to fund a previously announced $3.0 million registered direct offering. The judgment awarded the Company $3.0 million plus attorneys' fees and applicable interest, and the Company is pursuing enforcement and collection.

The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 is available through the SEC Filings section of Inhibitor Therapeutics' Investor Relations website. Review the August 14, 2026 Form 10-Q

2026 Annual Meeting of Stockholders

Inhibitor also reminds stockholders that its 2026 Annual Meeting of Stockholders will be held virtually on September 15, 2026 at 10:00 a.m. Eastern Time. The Company encourages stockholders to vote in advance even if they plan to attend the virtual meeting.

Stockholders who have not yet voted should review their proxy materials and submit their voting instructions as soon as possible. Votes may be submitted online at ProxyVote.com using the 16-digit control number included with the proxy materials, by telephone at 1-800-690-6903, or by returning the proxy card by mail. Internet and telephone voting before the meeting remains available until 11:59 p.m. Eastern Time on September 14, 2026. Eligible stockholders may also vote electronically during the virtual Annual Meeting.

The Board of Directors' recommendations and complete information regarding the matters to be voted upon are contained in the definitive proxy statement. Stockholders are encouraged to review those materials and ensure their shares are represented at the Annual Meeting. Review the 2026 proxy statement Attend the virtual Annual Meeting

About Inhibitor Therapeutics

Inhibitor Therapeutics, Inc. is a pharmaceutical development company focused on developing and ultimately commercializing innovative therapeutics based on FDA-approved active pharmaceuticals that have patent-protected methods of use and/or methods of delivery for patients with certain cancers and certain non-cancerous proliferation disorders. The Company's current primary focus is the development of itraconazole for basal cell carcinoma nevus syndrome, also known as Gorlin Syndrome.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of applicable federal securities laws, including statements regarding the Company's proposed regulatory strategy and efficacy endpoint, interpretation of HP2001 and external-control evidence, the potential 505(b)(2) pathway, future FDA interactions and written responses, formulation-development and comparative-bioavailability plans, intellectual-property strategy, potential market opportunity, enforcement and collection of the Delaware judgment, and the potential development, approval and commercialization of itraconazole for BCCNS. Forward-looking statements are based on current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially.

Among other risks, FDA may reach different conclusions regarding the Company's proposed endpoint, descriptive readings of the HP2001 data, external-control approach or regulatory pathway and may require additional clinical, nonclinical, pharmacokinetic, chemistry, manufacturing and controls, or other evidence before a marketing application may be submitted or approved. HP2001 was an open-label, single-arm study; the readings described above are descriptive characterizations of prospectively collected measurements and should not be interpreted as prospectively specified inferential tests or as head-to-head

treatment-effect estimates against the separate Tang vismodegib study. Future comparative-bioavailability work may not achieve its intended objectives, patent applications may not result in issued or enforceable patents, illustrative commercial assumptions may not be realized, and the Company may not recover all or any portion of the Delaware judgment. Additional risks are described in the Company's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q filed August 14, 2026 and Annual Report on Form 10-K for the year ended December 31, 2025. The Company undertakes no obligation to update forward-looking statements except as required by law.

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INHIBITOR THERAPEUTICS

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