



NEWS RELEASE

Castle Biosciences Highlights Progress for its Pipeline Atopic Dermatitis Gene Expression Profile Test

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Assuming successful validation, the Company currently expects to launch the pipeline test by the end of 2025

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today provided an update on its test currently in development for use in patients diagnosed with moderate-to-severe atopic dermatitis (AD) who are seeking systemic treatment. Based on preliminary data from the Company's ongoing prospective development and validation study, Castle's pipeline test has shown potential to identify a subset of patients with AD who have an increased likelihood to achieve a super response to targeted therapies, indicated by a 90% or greater reduction in Eczema Area and Severity Index (EASI) score (EASI90) at three months. Assuming successful validation, the Company currently expects to launch its pipeline test by the end of 2025.

"It is estimated that there are more than six million patients diagnosed with moderate-to-severe AD in the U.S. seeking treatment annually, and approximately 760,000 of these patients seek systemic treatment," said Derek Maetzold, president and chief executive officer of Castle Biosciences.^{1,2} "Today, once a clinician and patient determine that systemic therapy is needed to control the patient's AD, a 'trial-and-error' treatment cycle begins. This 'trial-and-error' approach results in approximately 25% of patients discontinuing their initial systemic therapy.³ Separately, approximately 50% of patients who stay on their initial therapy have indicators of persistent disease burden.⁴

"Data from our ongoing validation study for our pipeline test suggests we may be able to improve the standard-of-care 'trial-and-error' treatment approach by identifying patients who are more likely to achieve a super response to



a specific class of therapy based on identification of the immune pathway that is driving their AD. By targeting validation of the test to predict a 90% or greater reduction in disease severity by three months, instead of the traditional standard of 75% reduction, this test provides information on an endpoint used in current drug development that we anticipate will be more relevant for the future (EASI90).

“Using a molecular test to identify the disease-driving immune pathways and to inform the class of drugs a patient could initiate based on increased likelihood of achieving a super response provides a precision medicine tool to increase the number of patients achieving a super response in less time by reducing ‘trial-and-error,’ which may reduce the utilization of healthcare resources.”

Castle has enrolled more than 1,100 patients across 39 active clinical study sites (as of Sept. 30, 2024) for this development and validation study. Follow-up is ongoing with many of these patients, as the Company is assessing response at three months, which is the first typical timepoint for clinicians and patients to determine if the current therapy is effective. Launch strategy planning for the Company's pipeline test, including selecting the reimbursement pathway, is ongoing.

About Castle's Atopic Dermatitis Pipeline Program

Atopic dermatitis (AD) is among the most common inflammatory skin condition, and patient quality of life is severely impacted by this chronic disease. It is estimated that there are more than six million patients diagnosed with moderate-to-severe AD in the U.S. seeking treatment annually, and approximately 760,000 of these patients seek systemic treatment. The Castle test in development analyzes the expression of hundreds of genes to potentially identify patients who have increased likelihood to achieve a super response to targeted therapies, indicated by a 90% or greater reduction in Eczema Area and Severity Index (EASI) score (EASI90) at three months. Using a molecular test like Castle's pipeline test to identify the disease-driving immune pathways and to inform the class of drugs a patient could initiate based on likelihood of achieving a super response provides a precision medicine tool to increase the number of patients achieving a super response in less time by reducing trial-and-error, which may reduce the utilization of healthcare resources.

About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a leading diagnostics company improving health through innovative tests that guide patient care. The Company aims to transform disease management by keeping people first: patients, clinicians, employees and investors.

Castle's current portfolio consists of tests for skin cancers, Barrett's esophagus, mental health conditions and uveal melanoma. Additionally, the Company has active research and development programs for tests in these and other

diseases with high clinical need, including its test in development for use in patients diagnosed with moderate-to-severe atopic dermatitis who are seeking systemic treatment. To learn more, please visit www.CastleBiosciences.com and connect with us on [LinkedIn](#), [Facebook](#), [X](#) and [Instagram](#).

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Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created by those sections. These forward-looking statements include, but are not limited to, statements concerning: the ability of Castle’s pipeline AD gene expression profile test to (i) identify a subset of patients with AD who have increased likelihood of achieving a super response to targeted therapies, (ii) advance the disease state and treatment response standards and (iii) help inform the class of drugs a patient should initiate; and the timing and achievement of anticipated operational milestones such as test validation, determining a reimbursement pathway and test launch and commercialization. The words “believe,” “can,” “could,” “potential” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation: subsequent study or trial results and findings may contradict earlier study or trial results and findings or may not support the results obtained in these studies, including with respect to the discussion of our tests in this press release; actual application of our tests may not provide the aforementioned benefits to patients; and the risks set forth under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

¹ <https://nationaleczema.org/research/eczema-facts/#:~:text=Overall%2C%2060%25%20of%20individuals%20with,10%25%20of%20children%20under%2018>

² Epidemiology of atopic dermatitis in adults: Results from an international survey, *Allergy* .2018;1284-1293. DOI: 10.1111/all.13401

³ Fichenfield, J. E., DiBonaventura, M., Xenakis, L., et al. (2020). Costs and treatment patterns among patients with

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atopic dermatitis using advanced therapies in the United States: Analysis of a retrospective claims database. *Dermatology and Therapy*, 10, 791–806. <https://doi.org/10.1007/s13555-020-00413-8>

⁴ Quick, A. P., Hurton, L. V., Zolocheska, O., Farberg, A. S., Goldberg, M. S., & Silverberg, J. I. (2024). Contemporary systemic treatment patterns in atopic dermatitis. *British Journal of Dermatology*, 191(Suppl. 2). <https://doi.org/10.1093/bjd/ljae266.081>

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