agenus

NEWS RELEASE

France Expands National AAC Access for Agenus' Botensilimab + Balstilimab for Ovarian Cancer and Soft-Tissue Sarcomas

2026-01-12

Updated national AAC protocol supports hospital-based, fully-reimbursed compassionate access across three solid tumor settings

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc**. (Nasdaq: AGEN), a leader in immuno-oncology innovation, today announced that France's National Agency for Medicines and Health Products Safety (ANSM) has approved an updated national treatment protocol for botensilimab (BOT) plus balstilimab (BAL) under France's Autorisation d'Accès Compassionnel (AAC) framework.

The updated protocol expands France's previously granted AAC authorization for BOT+BAL in patients with microsatellite-stable (MSS) metastatic colorectal cancer (mCRC) without active liver metastases to eligible patients with certain ovarian cancers and soft-tissue sarcomas—diseases with substantial unmet medical need after standard options have been exhausted.

The revised protocol is designed to broaden the eligibility criteria, allowing more patients with advanced solid tumors to have early access to BOT+BAL under reimbursed compassionate use, and to enhance monitoring and treatment procedures in participating hospitals.

BOT+BAL is a chemotherapy- and radiation-free immunotherapy combination being evaluated in clinical studies and available in compassionate access settings authorized by ANSM. In studies conducted to date, antitumor activity has been observed in heavily pretreated patients, including in tumor types that have historically shown limited responsiveness to standard immunotherapy approaches.

France's AAC pathway enables hospital-based access for patients with serious or life-threatening diseases who lack appropriate therapeutic alternatives. Treatment under AAC is governed by a national protocol that standardizes the conditions of use, including patient eligibility, treatment administration, effectiveness and safety data collection and follow-up under France's national health system oversight.

For eligible French patients treated in hospital under AAC, BOT+BAL is fully reimbursed.

Expanded AAC eligibility

Under the updated national protocol, reimbursed AAC access to BOT+BAL is authorized in France for eligible adult patients with:

- MSS metastatic colorectal cancer without active liver metastases, following progression on standard therapies;
- Platinum-refractory or platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, after exhaustion of approved treatment options; and
- Advanced or metastatic soft-tissue sarcomas, including multiple high-grade histologies, following failure of standard therapies.

Significance of the update

By extending fully reimbursed AAC access across colorectal cancer, ovarian cancer, and sarcoma, France has implemented a multi-tumor early access framework for a single investigational immunotherapy combination under one nationally standardized protocol. This represents an uncommon level of national early-access authorization and enables consistent hospital access to an investigational treatment while maintaining ANSM oversight and structured patient follow-up as additional clinical and real-world evidence continues to develop.

BOT+BAL remains investigational and is not approved for commercial marketing in France or elsewhere.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer with a comprehensive pipeline of immunological agents. The company was founded in 1994 with a mission to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants. Agenus has robust end-to-end development capabilities, across commercial and clinical cGMP manufacturing facilities, research and discovery, and a global clinical

operations footprint. Agenus is headquartered in Lexington, MA. For more information, visit **www.agenusbio.com** or @agenus_bio. Information that may be important to investors will be routinely posted on our website and social media channels.

Agenus is committed to responsible patient access to investigational medicines through clinical trials and regulatory-authorized early-access mechanisms. In France, BOT+BAL is available only through the ANSM-authorized AAC framework under a nationally validated protocol, with full government reimbursement for eligible patients treated in hospital.

About Global Access Pathways

Until marketing authorization is granted, BOT+BAL is accessible only through clinical trials including the Phase 3 BATTMAN trial in refractory MSS colorectal cancer and authorized early access mechanisms where permitted and available under each country's regulatory framework.

For eligible French patients treated in hospital under AAC meeting the pre-defined criteria, BOT+BAL is fully reimbursed by France's national health system (Assurance Maladie). Reimbursement is structured as a single, upfront, course-based reimbursement per patient that covers the patient's full course of therapy according to the national AAC protocol, rather than on a per-dose basis. Once a patient is authorized and treatment is initiated under the protocol, full course of treatment and all subsequent administrations are supplied without additional product charges. In line with AAC requirements, the maximum indemnity applicable to BOT+BAL is declared to the relevant French authorities.

Outside France, access may be available in select countries through paid named-patient programs, which may involve out-of-pocket payment and/or special insurance arrangements depending on local regulations and individual coverage decisions.

About Botensilimab (BOT)

Botensilimab (BOT) is a human Fc-enhanced multifunctional anti-CTLA-4 antibody designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend immunotherapy benefits to "cold" tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. Botensilimab augments immune responses across a wide range of tumor types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Approximately 1,200 patients have been treated with botensilimab and/or balstilimab in phase 1 and phase 2

clinical trials. In France, botensilimab is accessible only through the ANSM-authorized AAC framework when used as BOT+BAL under the national protocol described above.

About Balstilimab (BAL)

Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. It has been evaluated in more than 900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types. In France, balstilimab is accessible only through the ANSM-authorized AAC framework when used as BOT+BAL under the national protocol described above.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding botensilimab and balstilimab, early access pathways, clinical development plans (including BATTMAN), and expected regulatory and clinical timelines, and any other statements containing the words “may,” “believes,” “expects,” “anticipates,” “hopes,” “intends,” “plans,” “forecasts,” “estimates,” “will,” and similar expressions intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Annual Report on Form 10-K for 2024, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

Investors

917-362-1370 | **investor@agenusbio.com**

Media

781-674-4422 | **communications@agenusbio.com**

Source: Agenus Inc.