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NEWS RELEASE

Agenus Expands Medical Affairs Infrastructure to Support Increasing Physician Requests for Authorized Access to Botensilimab Plus Balstilimab

2026-01-21

Medical Affairs scale-up supports France's multi-tumor AAC access framework and expanding paid named-patient programs requests

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus** Inc. (Nasdaq: AGEN), a leader in immuno-oncology innovation, today announced the expansion of its global Medical Affairs infrastructure and early-access support capabilities in response to increasing physician-initiated interest regarding authorized access to the investigational immunotherapy combination botensilimab plus balstilimab (BOT+BAL).

The expansion reflects increasing interest from treating oncologists worldwide seeking access to BOT+BAL for patients with advanced solid tumors through regulatory-authorized early access pathways, including France's Authorisation d'Accès Compassionnel (AAC) framework and paid named patient programs (NPPs) where permitted. This interest follows a series of recent scientific milestones, including peer-reviewed publications, clinical data presentations at major international scientific meetings and the recent expansion of reimbursed compassionate access for BOT+BAL under France's AAC framework that now includes three tumor types.

This scientific and regulatory validation has translated into real-world physician action. Patients have already been treated with BOT + BAL through regulatory-authorized paid named patient programs in multiple countries across South and Central America and Europe, including the United Kingdom and Switzerland, where permitted by local regulations. These requests have originated from treating oncologists managing patients with advanced solid tumors who have exhausted available standard-of-care treatment options, and require coordinated Medical Affairs oversight to support compliant access, safety monitoring, and regulatory alignment across regions.

Botensilimab is an Fc-enhanced multifunctional anti-CTLA-4 antibody, and BAL is an PD-1 inhibitor. Together, BOT+BAL is a chemotherapy- and radiation-free immunotherapy regimen currently being evaluated in clinical trials.

Authorized Early Access Pathways

Agenus' early-access support is structured around two complementary authorized pathways:

• France's AAC framework, under which BOT+BAL is provided in hospitals under a nationally standardized protocol and is reimbursed for eligible patients across three advanced solid tumors: MSS mCRC without active liver metastases, platinum-refractory or platinum-resistant ovarian cancer, and advanced or metastatic soft-tissue sarcomas; and

• Paid named-patient programs (NPPs) in select countries where permitted and available under each country's regulatory framework. These programs are physician-initiated and patient-specific and may involve out-of-pocket payment and/or special insurance arrangements depending on local regulations and individual coverage decisions.

"As clinical evidence for botensilimab plus balstilimab continues to mature, we are seeing increasing inquiries from physicians seeking information about access for patients with limited therapeutic alternatives," said Garo Armen PhD, Chairman and Chief Executive Officer of Agenus. "Expanding our global Medical Affairs infrastructure ensures that this interest is supported with the appropriate scientific rigor, safeguards, while positioning the organization for disciplined execution across authorized access pathways and late-stage clinical development."

As physician engagement and access requests have increased, Agenus has expanded its Medical Affairs infrastructure to ensure that requests are supported responsibly and in alignment with applicable regulatory guidelines. Medical Affairs plays a central role in facilitating scientific exchange, coordinating appropriate access requests where permitted, supporting pharmacovigilance and safety reporting, and enabling structured collection of real-world safety and outcomes data where applicable.

BOT+BAL remains investigational and is not approved for commercial marketing in France or elsewhere. In the United States, access to BOT+BAL is currently limited to participation in clinical trials, consistent with applicable regulatory requirements for investigational therapies.

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.

Global access pathways

Until marketing authorization is granted, BOT+BAL is accessible only through clinical trials including the planned 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 BATTMAN CO.33 Phase 3 Trial

Agenus, in collaboration with the Canadian Cancer Trials Group (CCTG), is initiating a global Phase 3 registrational trial evaluating botensilimab (BOT) plus balstilimab (BAL) versus best supportive care (BSC) in patients with refractory, unresectable microsatellite stable (MSS)/mismatch repair proficient (pMMR) colorectal cancer. The study will be conducted as an international cooperative group trial, led by CCTG and supported by academic networks including AGITG (Australasian Gastro-Intestinal Trials Group) and PRODIGE (France), which comprises Unicancer, GERCOR, and FFCD. The trial will enroll approximately 800 patients across more than 100 sites in Canada, France, Australia, and New Zealand.

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.

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Source: Agenus Inc.