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Biotechnology & Health:

US FDA Grants Fast Track Designation for Gene Therapy: The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to AAVantgarde Bio's gene therapy program, AAVB-039, for treating Stargardt disease. This is a significant step for the clinical-stage company as the designation is intended to expedite the development and review of therapies for serious or life-threatening conditions with unmet medical needs. Stargardt disease is the most common inherited form of macular degeneration and a leading cause of vision loss in children and young adults, with no approved treatments currently available.

BioNTech Launches New Clinical Trial Platform in Australia: BioNTech, in partnership with Australia's Peter MacCallum Cancer Centre, has launched a new Clinical Trial Platform to improve access for cancer patients to investigational therapies for hard-to-treat cancers. The platform is designed to streamline clinical trials and offer more treatment options for patients with various common cancers, including lung, breast, and melanoma. This initiative is part of a broader strategic partnership that includes establishing an mRNA manufacturing facility in Victoria.

India's Department of Biotechnology (DBT) and BIRAC Call for Proposals: The Department of Biotechnology (DBT) and the Biotechnology Industry Research Assistance Council (BIRAC) have issued a joint call for proposals. The deadline for two of these calls is today, August 14, 2025: one for "Futuristic Marine research" and another for "Biomanufacturing of Bio-Based Chemicals, Biopolymers and Active

Pharmaceutical Ingredients (APIs) in Production Strains" under the BioE3 Policy. This highlights India's ongoing push to foster innovation and become a global biomanufacturing hub.

Company Financial Reports: Several biotechnology and biopharmaceutical companies, including Protalix BioTherapeutics and BioLineRx, are scheduled to announce their second-quarter 2025 financial and business results today. These reports are closely watched by investors and industry analysts to gauge the companies' performance and future outlook.

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MCQS

1. What is the purpose of the Fast Track Designation granted by the U.S. FDA to AAVantgarde Bio's gene therapy program, AAVB-039?

- a) To provide immediate approval for the therapy.
- b) To expedite the development and review of the therapy for serious conditions.
- c) To fund the clinical trials for the therapy.
- d) To declare the therapy as a cure for Stargardt disease.

Answer: b) To expedite the development and review of the therapy for serious conditions.

The news states that the FDA's Fast Track Designation is intended to "expedite the development and review of therapies for serious or life-threatening conditions with

unmet medical needs," which in this case is Stargardt disease.

2. In which country has BioNTech partnered with the Peter MacCallum Cancer Centre to launch a new Clinical Trial Platform?

- a) United States
- b) Germany
- c) India
- d) Australia

Answer: d) Australia

The news report clearly mentions that BioNTech, in partnership with Australia's Peter MacCallum Cancer Centre, has launched a new Clinical Trial Platform in Australia.

3. What is the focus of one of the proposals called for by India's Department of Biotechnology (DBT) and the Biotechnology Industry Research Assistance Council (BIRAC) with a deadline of August 14, 2025?

- a) Developing new vaccines for infectious diseases.
- b) Clinical trials for cancer treatments.
- c) Biomanufacturing of Bio-Based Chemicals, Biopolymers and Active Pharmaceutical Ingredients (APIs).
- d) Research on space medicine.

Answer: c) Biomanufacturing of Bio-Based Chemicals, Biopolymers and Active Pharmaceutical Ingredients (APIs).

The news highlights two specific calls for proposals with a deadline of August 14, 2025. One of them is for "Biomanufacturing of Bio-Based Chemicals, Biopolymers and Active Pharmaceutical Ingredients (APIs) in Production Strains" under the BioE3 Policy.

4. For which disease has the U.S. FDA granted Fast Track Designation to AAVantgarde Bio's gene therapy, AAVB-039?





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- a) Lung cancer
- b) Stargardt disease
- c) Melanoma
- d) Macular degeneration in adults

Answer: b) Stargardt disease

The news specifies that the Fast Track Designation was granted to AAVantgarde Bio's gene therapy program, AAVB-039, for treating Stargardt disease, which is the most common inherited form of macular degeneration.

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