Bayer in Berkeley

Cell and Gene Therapy Production Center Will Serve Growing Need for Specialized Medicines

This production facility represents a new generation of campus infrastructure which will enable agile and flexible manufacturing. The building is designed to allow for development and launch of a variety of treatments.

The project will create flexible production suites that can meet varying levels of demand to supply various stages of clinical trials of medicines (development) and early commercial supplies (launch). Initially, Bayer envisions that this building would house the production of cell or gene therapies to treat conditions such as Parkinson’s disease or heart failure. The design flexibility also allows for the building to produce high volumes of a single drug therapy if patient demand requires rapid scale up.

The proposed Cell and Gene Therapy Production Center conforms with the 1992 Development Agreement (DA) between Bayer and the City of Berkeley, which includes provisions to enable specialized biotech production facilities along the western portion of the campus.

Project Parameters
- **Square feet:** ~98,000
- **Zoning District:** Mixed Manufacturing (MM) as supplemented by Development Agreement terms
  - Complies with DA height restrictions
  - Three stories + mechanical/HVAC penthouse story, totaling 80 feet
  - Limited visibility from Aquatic Park due to tree coverage
- **Operations:** 24/7 building operation
- **Biosafety level:** 2 (the same biosafety level as a clinical/hospital diagnostic laboratory)
- **Structure estimated completion:** December 2022

Sustainability Features
- Seeking LEED Certification (targeting Silver level)
- Complies with proposed bird-safe glass ordinance
- Solar Photovoltaic (PV) ready
  - PV would have no visual impact.
  - Building PV part of site-wide PV plan to support Bayer’s target to be carbon neutral by 2030
- Berkeley natural gas ban compliant
- Courtyard area with sustainable bio-retention planter
- No additional auto parking on site needed; expanding on-site bike parking

Designed for Flexibility and Efficiency
The Cell and Gene Therapy Production Center houses production modules that can be readily reconfigured to produce a variety of products in a range of volumes. This flexibility drives the size and shape of the floorplate based on the process anticipated for cell therapy production. The stacked configuration improves efficiency. Shared support areas and co-
located personnel deliver process efficiency, while shared services on the mechanical floor increase energy efficiency.

Public Review Process Underway with the City of Berkeley

The 1992 DA requires that the Design Review Committee (DRC) and the Zoning Adjustments Board (ZAB) review for buildings exceeding 40,000 square feet. The DRC is a subcommittee of the ZAB and reviews and approves of design proposals for all projects in commercial, manufacturing and some residential zoning districts. The ZAB grants, denies, adds conditions of approval or modifies applications for Use Permits in accordance with City codes. Following authorization of a Use Permit by the ZAB, applicants such as Bayer can proceed through building permitting steps and, ultimately, to construction activities.

- DRC meeting: January 21
- ZAB meeting: anticipated March 11

This Facility and Bayer’s Berkeley Campus Today and Tomorrow

Bayer’s biopharmaceutical operations are located about 2.5 miles from downtown Berkeley along the western edge of the city. The site encompasses 46 acres of manufacturing and laboratory space as well as administrative offices. More than 1,000 Berkeley campus employees develop new products and manufacture Bayer’s three commercially marketed treatments that help people with hemophilia A lead more active lives with this rare disease.

For the past 30 years, the Berkeley site has largely been dedicated to the development and manufacture of medicines for people with hemophilia A – a rare, genetic blood disorder in which their bodies do not produce an important blood clotting protein called Factor VIII. The medicines are called recombinant protein therapeutics and are essentially genetically engineered copies of the protein that people with hemophilia A cannot produce on their own. Prior to the introduction of Factor VIII products, individuals with hemophilia A were at risk of life-threatening bleeding events that could be caused by what most of us consider to be everyday activities. Bayer introduced its first recombinant Factor VIII product in 1993 and continues to market three such products today. These are some of the largest and most complex protein therapeutics manufactured.

In 2019 Bayer broke ground on its Cell Culture Technology Center. This center, which is expected to become operational at the end of 2021, will support the production of multiple medicines classified as monoclonal antibodies. Monoclonal antibodies are bioengineered molecules that are designed to target specific proteins involved in disease.

Building on its strong foundation in biologics development and biomanufacturing in Berkeley, Bayer plans to diversify operations. In 2020, Bayer submitted its proposed master plan for the transformation of its Berkeley campus along with its application to extend the current Development Agreement between Bayer and the City of Berkeley.

The company will be continuing to invest in new facilities and technologies that speed the development and launch of specialty medicines. New plans for the site will accommodate current hemophilia treatment manufacturing activities in a smaller footprint and evolve to meet the needs of specialty medicine. Just as it did in bringing forward its recombinant Factor VIII therapies to patients, Bayer plans to leverage breaking scientific advances and cutting-edge facilities to accelerate next generation medicines for patients living with challenging medical conditions such as cancer, cardiovascular or Parkinson’s diseases.