Government development of ‘made-in-Canada’ CAR-T cell immunotherapies: assessing cost, risk, access, and alternatives

Description

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ABSTRACT

Summary: Chimeric Antigen Receptor T, or CAR-T cell immunotherapy, is a novel treatment that genetically engineers a patient’s own T-cells to recognize and attack cancer cells. CAR-T therapeutics have been available in the United States since May 2017, and in Canada since September 2018. As of July 1, 2024, six CAR-T products had been authorized for marketing by both the U.S. Food and Drug Administration (FDA) and Health Canada. One drug was later withdrawn from the Canadian market. Health technology assessment (HTA) is a prerequisite of the public reimbursement process in Canada and is conducted by the Canadian Drug Agency (CDA), formerly known as the Canadian Agency for Drugs and Technologies in Health (CADTH). The five commercially available CAR-T products were recommended for public reimbursement by CDA. However, the prices for these therapies exceeded the cost effectiveness threshold used by CDA and therefore its recommendations were conditional on pricing adjustment. CAR-T has been eligible for public funding under US Medicare since 2017. By contrast, as of July 1, 2024, only six of the 10 Canadian provinces have authorized CAR-T products for public reimbursement. Lack of public funding is a significant barrier to accessing CAR-T immunotherapy, in addition to several other obstacles to treatment affecting patient access. Federal and provincial governments have been reluctant to extend funding eligibility for commercial products, preferring instead to invest in public development of a made-in-Canada capacity for manufacturing CAR-T therapies. Alternative funding models could more efficiently and more immediately improve access using commercially available CAR-T therapies in Canada.

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ERRATA

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The following paragraph on page 6 of the original publication contained some inaccuracies: “Over the last 10 years, the federal government has publicly funded BioCanRx., which was incorporated in 2014 as a not?for?profit organization, and is essentially a government-sponsored enterprise (GSE) established to provide “operational support” for “decentralized”, “point of care” biomanufacturing capacity in Canada for novel therapies like CAR-T. From 2015 to 2023, BioCanRx received almost $120 million primarily from federal government sources like the National Centres of Excellence, and the Strategic Science Fund, a program of Innovation, Science and Economic Development Canada.”

In fact, BioCanRx annual reports and financial statements indicate that the organization received at least $118 million including $40 million for the years 2014 to 2024 from the federally funded Networks of Centres of Excellence of Canada, plus $38 million for 2024 to 2028 from the federally funded Strategic Science Fund, and the remainder being at least $40 million (including non-cash support) over the years 2014 to 2024 from its “Partners” which include publicly funded universities and hospitals, as well as commercial enterprises that have private and public sources of start up capital.

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