

**Testimony of Beth A. Garvy, Ph.D.,  
on behalf of The American Association of Immunologists (AAI),  
Submitted to the Senate Appropriations Subcommittee on  
Labor, Health and Human Services, Education, and Related Agencies,  
Regarding the Fiscal Year 2019 Budget for the National Institutes of Health  
May 18, 2018**

The American Association of Immunologists (AAI), the nation's largest professional society of research scientists and physicians who study the immune system, respectfully submits this testimony regarding fiscal year (FY) 2019 appropriations for the National Institutes of Health (NIH). **AAI recommends an appropriation for NIH of at least \$39.3 billion for FY 2019** to enable NIH to fund critically important new and ongoing biomedical research, support the next generation of biomedical researchers, and ensure continued robust investment in this national priority area

treatment of some solid tumors and blood cancers, was also recently approved for treatment of cancers with a specific genetic feature (biomarker). This recent approval of pembrolizumab (Keytruda<sup>®</sup>) is significant not only because of the responses that are being achieved (~40% complete or partial response), but also because this was the first FDA approval given to a therapy based on a biomarker rather than on the tumor's original location in the body.<sup>4</sup> Subsequently, nivolumab (Opdivo<sup>®</sup>) received approval for treatment of colorectal cancer with a specific biomarker.<sup>5</sup> These advances directly result from NIH-funded research demonstrating the sensitivity of tumors harboring these genetic features to immunotherapy.<sup>6</sup>

**Hepatitis B vaccine** - Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer, and death. An estimated 850,000 – 2.2 million people in the U.S. have chronic hepatitis B, resulting in approximately 1,800 deaths every year.<sup>7</sup> There is no cure, and infections are on the rise. Over the past decade, however, NIH has provided more than \$17 million toward the development of vaccine adjuvants (which enhance vaccine efficacy).<sup>8</sup> In 2017, the FDA approved HEPLISAV-B, the first new vaccine for the hepatitis B virus (HBV) in 25 years.<sup>9</sup> Because HEPLISAV-B requires only two doses over one month, in contrast to previously available vaccines, which require three doses over six months, this new vaccine may be a valuable tool in the effort to improve vaccination rates and therefore prevent infection with, and death from, HBV.

**Artificial pancreas for type 1 diabetes** – Type 1 diabetes (T1D) is an autoimmune disease that affects over 1.25 million Americans, including 200,000 children.<sup>10</sup> People with T1D are unable to produce insulin because their immune system has destroyed their insulin-producing (i.e., beta) cells, resulting in an uncontrolled rise in blood sugar levels. Complications from T1D include blindness, nerve damage, kidney failure, heart disease, and death. Because changes in diet or lifestyle alone will not treat the disease, diabetic patients must closely monitor their blood sugar levels to ensure that they are taking the needed dose of insulin.<sup>11</sup> Control of blood sugar levels is essential to preventing or delaying T1D complications. NIH-funded researchers from fields including immunology, endocrinology, bio-engineering, and computational biology have developed “closed-loop” artificial pancreas systems, which continuously monitor blood sugar and automatically admini0 Tw 12 -e dag T1D coutions.lp-6(a)4(r)ial

associated with every single one of the 210 new drugs approved by the [FDA] from 2010 through 2016 [and that] [m]ore than 90 percent of that contributory research was basic – that is, related to the discovery of fundamental biological mechanisms, rather than actual development of the drugs themselves.”<sup>16</sup>

NIH also provides invaluable scientific leadership both in the U.S. and abroad. The steward of more than \$37 billion in taxpayer dollars, NIH advises our nation’s elected and appointed leaders on scientific advancements, needs, and threats, and works to ensure that its funds are properly and prudently spent. NIH not only governs the conduct of scientific research at academic institutions in the U.S., it also fosters collaborations between U.S.-based scientists and their invaluable international colleagues; and between government and the pharmaceutical, biotechnology and medical device industries, all of which benefit from NIH-supported research to fuel their own advances.

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413-420.; Rosenberg, S. A. et al. 1988. Use of tumor-infiltrating lymphocytes and interleukin-2 in the immunotherapy of patients with metastatic melanoma. N. Engl. J. Med 319: 1676-1680.

<sup>2</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm>

<sup>3</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm581216.htm>

<sup>4</sup> <https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm560040.htm> [approval for two biomarkers: microsatellite instability high (MSI-H) and mismatch repair deficient (dMMR)]

<sup>5</sup> <https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm560040.htm> (approval for MSI-H and dMMR)

<sup>6</sup> Le, D. T. et al. 2017. Mismatch repair deficiency predicts response of solid tumors to PE6.12 Tm3(a)4msfi4T(7 Tw 0.253 0(ppr)14(c