CLOSER LOOK

MEMORANDUM

Type 1 diabetes cures and prevention competitive landscape – March 19, 2026

- **We have updated our type 1 diabetes cures and prevention competitive landscape following several key advances in the field. See updates in the appendix below the table.**
- **The table below includes an overview of the competitive landscape for type 1 diabetes cure or prevention therapies.** It includes all the companies we are aware of with projects in development for beta cell replacement, immune therapy, or other approaches with the aim of preventing, delaying, slowing, or curing type 1 diabetes. We will continuously update the table as timelines change. Our glucose-responsive insulin and automated insulin delivery competitive landscapes are hosted on separate pages.

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Beta Cell Encapsulation

Company	Product	Type	Status	Timeline
ViaCyte	PEC-Direct (VC-02)	Stem-cell derived pancreatic progenitor cells requiring immunosuppression	Phase 1/2	Preliminary results published in Nature 2023: 4 of 10 patients maintained **stimulated C-peptide ≥0.1 nmol/L** at 12 months, with improved glucose control and reduced insulin requirements **Six of 17** participants had detectable C-peptide in prior 2021 update Phase 1/2 initiated in the US and Europe; EU program began in January 2019 Targeted for high-risk T1D patients with severe hypoglycemia or renal failure.
ViaCyte/ CRISPR Therapeutics	PEC-QT	Islets are derived from genetically engineered stem cells that are immune-evasive	Phase 1	Completed in January 2023; announced the first patient dosed in the phase 1 trial in February 2022; Health Canada approved initiation of a Phase 1 trial of immune-evasive, stem cell-derived therapy for the treatment of T1D inNovember 2021;"Moving into pre-IND activities" as of May 2020; Preclinicaldata reported at EASD in 2019 showed gene-edited immune-evasive cells demonstrated *in vitro*protection against activated T-cells compared to controls;Announced at JPM 2018; Received $1.4 million from CIRM for development of immune-evasive stem cells in December 2017; Subsequently partnered with CRISPR Therapeutics.
Adocia	AdoShell Islets	Immune-protective biomaterial for islet	Preclinical	New preclinical data presented at ATTD 2025 showed sustained human C-peptide

		transplantation		secretion for three months in minipig models. Additional data will be presented at ADA 2025, IPITA World Congress, European Islet Study Group, and the International Society for Cell and Gene Therapy. IND-enabling studies are ongoing with a first-in-human trial submission planned for 2H25.
Kadimastem	IsletRx	Microencapsulation platform containing pancreatic insulin-secreting islets generated from embryonic stem cells	Preclinical	Merger announced with NLS Pharmaceutic in February 2025, with IsletRx remaining a focus of the merger.
Novo Nordisk/ UCSF/ Cornell	Undisclosed	Stem cell derived insulin producing cells	Preclinical	Preclinical updates shared at EASD 2022; collaboration announced May 2018.
Seraxis Therapeutics	SR-02	Replacement pancreatic islet cells	Phase 1/2	The allogeneic pancreatic endocrine cell clusters are under study in phase 1/2 in adults with T1D with severe, recurrent hypoglycemia. Immunosuppression is required. The study is expected to complete in 2027.
Seraxis Therapeutics	SR-03	Genetically modified pancreatic cell line islet replacement therapy	Preclinical	Awarded a $400,000 Commercialization Program grant from the Maryland Stem Cell Research Fund, which will accelerate the validation and manufacturing of the company's genetically modified pancreatic cell line SR-03 that that will not require lifelong anti-rejection immune suppression as a functional cure for the broader T1D and insulin-requiring T2D population.
Vertex	VX-264	Device encapsulation of VX-880 cells to eliminate the need for immunosuppression	Discontinued	Program discontinued in March 2025, following Part B Day-90 results, which showed that while the device was safe and well tolerated, but failed to deliver meaningful increases in C-peptide production. Part A of the trial completed and Part B initiated in 4Q23; FDA cleared IND in March 2023; trial in Canada ongoing and US trial expected to initiate in 1H23.

Beta Cell Replacement Sources

Company	Product	Type	Status	Timeline
Vertex/Semma Therapeutics	VX-880 (zimislecel)	Stem cell-derived insulin producing cells	Phase 1/2/3	**All 12 participants** in the **phase 1/2** FORWARD **trial**demonstrated **engraftment**, with **10**

				achieving insulin independence and **>90% time in range (TIR)** shown ADA 2025; Regulatory submission for approval is expected in 2026 as of 1Q25; VX-880 named **zimislecel at** JPM 2025**;** Zimislecel advanced into a **pivotal phase 1/2/3 trial**(n=52) in 3Q24; positive phase 1/2 results also highlighted at DUK 2025, ATTD 2025, and EASD 2024. Resumed following a protocol-specified pause announced in January 2024 after two unrelated patient deaths; Vertex has completed enrollment and dosing in Part B of the Phase 1/2 study of VX-880 and expects to present data at ADA 2023 in June; Vertex intends to begin Part C of the study with concurrent dosing; granted EMA designation in March 2023; Vertex acquires ViaCyte for $320 million in July 2022; FDA lifts clinical hold on phase 1/2 trial in July 2022; New CGM data for first two patients shared at ADA 2022, reinforcing extremely positive data for first patient; Positive data for first two patients released May 2022alongside announcement of FDA placing clinical hold on phase 1/2 trial; Preliminary data from phase 2 study released in October 2021 shows extremely promising results; Naked cell phase 1/2 launch and FDA Fast Track Designation received in March 2021; Naked

				cell program IND approved January 2021; Vertex on track to submit IND filing for islet cell transplant program in "late 2020," phase 2 to commence in 2021 as of 3Q20 update; Cell therapy to move into clinic by late 2020/ early 2021, as of JPM 2020; Semma acquired by Vertex Pharmaceuticals for $950 million in September 2019; Published in Nature in 2019 detailing improved beta cell generation/ purification process; Semma Therapeutics founded in April 2015 to translate Dr. Doug Melton's beta cell generation procedure into therapy.
Creative Medical Technology Holdings	CELZ-201	First novel allogenic cellular therapy in the dorsal artery of the pancreas	Phase 1/2	Announced positive one-year results of CELZ-201 in people with late-stage T2D in February 2025; Announced that partner, Greenstone Biosciences, has successfully developed a human induced pluripotent stem cell (iPSC) pipeline for the ImmCelz platform in May 2023; Announced positive topline results for cell therapy program in T2D in April 2023; Announced IRB approval of phase 1/2 trial of CELZ-201 as a treatment for recent onset T1D in February 2023; expected to initiate in 1Q23.
ViaCyte	VC-01, VCTX-211	Stem cell-derived insulin producing cells	Phase 1/2	Confirmed to still be in clinical testing as of Jan 2025. VCTX-211 continues to run in collaboration

				with CRISPR in a phase 1/2 study, expected to complete in August 2025. In 2006, ViaCyte published the first study demonstrating successful in vitro differentiation of human embroyonic stem cells into pancreatic tissue; In 2014 BetaLogics (now part of ViaCyte) published the first paper on using in vitro stem-cell derived beta cells to reverse diabetes in mice; ViaCyte is currently in phase 1/2 clinical studies with its stem cell-derived insulin producing cells.
Sernova	Cell Pouch Bio-hybrid Organ	Transplantation and engraftment of allogeneic islets for T1D	Phase 1/2	In July 2025, Sernova announced an agreement with Eledon Pharmaceuticals to evaluate Eledon's immunosuppressive agent tegoprubart (AT-1501), an investigational anti-CD40L antibody, in Sernova's ongoing phase 1/2 clinical trial. Tegoprubart would be used in place of tacrolimus, a standard immunosuppressivedrug used in organ transplantation to prevent rejection that has notable side effects and potential toxicity toward insulin-producing beta cells. As of September 2024, a phase 1/2 trial of the Cell Pouch in combination with allogeneic islets in T1D showed that all six participants in Cohort A achieved sustained insulin independence.
iTolerance, Inc.	ITOL-100	SA-FasL microgel to induce local immune	Preclinical	iTolerance enters collaboration agreement

		tolerance and enable allogeneic islet implantation		with Israeli-based Kadimastem and received $1 million from Isarel-US Industrial R&D Foundation in May 2023; iTolerance receives $850,000 from JDRF through Industry Discovery Development Partnership to support iTOL-100/101 program in June 2022; Results from preclinical trial released in May 2022; follows JDRF's former funding of iTOL-101's successful preclinical non-human primate study.
Pancryos	PanINSULA	PanINSULA stem cell-derived islet cell replacement	Preclinical	In May 2022, Pancryos announced a global exclusive license agreement with Brigham and Women's Hospital to combine PanINSULA with the Harvard Stem Cell Institute's convection-enhanced microencapsulation device.
Sana Biotechnology	SC451	Hypoimmune islet cell transplantation	Preclinical	IND filing for SC451 is planned for 2026. An investigator-sponsored trial using HIP-modified cells (a precursor to SC451) is expected to begin in late 2025. Additional mouse model data released March 2024 showed durable glycemic control for up to 15 months with no safety concerns. Preclinical data published in *Nature Biotechnology* in May 2023 showing survival of hypoimmune pluripotent stem cell-derived islets in non-human primate models for 40 weeks.

				Preclinical data published in April 2023, showing that hypoimmune human islet cells, engineered with CRISPR, successfully evaded immune rejection and normalized glucose levels in immunocompetent type 1 diabetes mouse models; an investigator-sponsored trial testing these cells in patients with T1D is expected to initiate later this year; aims to file IND in 2024 for SC451, hypoimmune stem cell-derived islet cell therapy.
Sanofi/Evotec	--	Functional stem cell-derived human beta cells for replacement therapies and for identification of active therapeutic targets	Preclinical	Evotec partners with Sernova to develop an islet replacement therapy combining Evotec's stem cell-derived beta cells with Sernova's Cell Pouch in May 2022; Evotec regains global rights to beta cell replacement therapy in April 2020, "exploring partnering options to bring this therapy to patients"; Sanofi discontinues R&D in diabetes in December 2019; Management expressed enthusiasm in January 2019 (interview); Partnership announced in August 2015.
Vertex/CRISPR	unnamed	Hypoimmune stem-cell derived insulin producing cells	Preclinical	Vertex and CRISPR Therapeutics announce $330 million non-exclusive licensing agreement for CRISPR/Cas9 gene editing technology in Vertex's type 1 diabetes hypoimmune cell therapy program in March 2023.
Lineage Cell	unnamed	Islet cell	Preclinical	Development of a

Therapeutics		transplantation program		scalable manufacturing process for islet cell transplantation to address barrier of large-scale islet cell production needed for commercial viability, announced in September 2025.
Sana Biotechnolgy	UP421	Hypoimmune primary islet transplantation	Early Clinical (Investigator-Sponsored)	As of June 2025, positive 6-month data show insulin production in response to meals, C-peptide presence, no adverse safety signals, and confirmed graft survival via PET/CT. Serves as clinical proof of concept for Sana's hypoimmune platform ahead of SC451.

Immune Therapies

Organization	Product	Type	Status	Timeline
Sanofi(formerly Provention Bio; formerly TrialNet)	Teplizumab	Anti-CD3	Approved Phase 4 for children <8 years Phase 3 extension trial	Phase 4 PETITE-T1D (n=20) for children under eight years and phase 3 PROTECT Extension trial (n=188) in people with recently diagnosed T1D ongoing, with expected completion in 2026. EU and China regulatory decisions expected 2H25, as of 1Q25. Teplizumab approved as Tzield in November 2022with dedicated conference calladdressing patient assistance; Provention and Sanofi enter co-promotion agreement in October 2022; Provention hosts investor event in May 2022; phase 3 PROTECT trialin newly diagnosed T1D to complete in May 2023; Teplizumab's original PDUFA date of August 17. 2022 was extended to November 17, 2022; Provention received a CRL from the FDA in July 2021; In January 2021ProventionBio filed the BLA with the FDA for type 1 diabetes delay, under the company's requested Priority Review, MAA filing in Europe slated for 2021, BLA submission completed to FDA with AdComm expected as of 3Q20 update; Follow-up data showing sustained delay of three years

				presented at ADA 2020; FDA Breakthrough Therapy Designation in August 2019; First therapy shown to delay type 1 diagnosis (ADA 2019); Phase 3 PROTECT study underway as of April 2019, following acquisition of candidate from MacroGeneics.
Nektar	rezpegaldesleukin	Treg	Phase 2	Nektar announced collaboration with TrialNet to study rezpegaldesleukin in people with new onset stage 3 type 1 diabetes mellitus (T1D) in February 2025.
St Vincent's Institute of Medical Research	baricitinib	Janus kinase (JAK) inhibitor	Phase 2	As *NEJM* published in December 2023, results of the phase 2 BANDIT study showed that in patients with recent onset T1D – diagnosed within 100 days of the study – 48 weeks of daily treatment with oral baricitinib, a Janus kinase (JAK) inhibitor known to block cytokine signaling, preserved beta-cell function, as measured by C-peptide level.
TrialNet	CTLA4-lg (abatacept)	Immunosuppressant	Phase 2	Dr. Danijela Tatovic (Cardiff University, UK) presented an overview of the SMART STUDY of combining IL-2 and abatacept at DUK 2025. Phase 2 trial was completed in 2022; preliminary results released in 2020 showed preservation of C-peptide levels and improvements in insulin sensitivity.
COUR Pharma	CNP-103	Antigen-specific immunotherapy	Phase 1b/ 2a	In August 2025, Chicago-based COUR pharma announced dosing of its first patient in its phase 1b/2a trial of CNP-103, a tolerogenic nanoparticle therapy, designed to induce antigen-specific immune tolerance in T1D. In addition to evaluating safety, the trial will assess whether CNP-103 can preserve islet cell function by maintaining C-peptide levels. The initial focus for this therapy is on stage 3 T1D patients, but COUR noted that CNP-103 has potential for stages 1 through 3 of T1D, as well as potentially later stages in combination with islet cell transplantations.
GentiBio	GNTI-122	Antigen-specific regulatory T cell therapy	Phase 1	In March 2026, GentiBio dosed first participant in the phase 1 POLARIS trial for new-onset T1D

Tr1X	TRX103	Type 1 regulatory (Tr1) cell therapy	Phase 1	In January 2024, Tr1X announced plans to evaluate TRX103 in a phase 1 trial to prevent Graft versus Host Disease (GvHD) in people undergoing mismatched hematopoietic stem cell transplant. Tr1X is also developing additional pipeline programs to treat inflammatory disease, multiple B-cell mediated autoimmune diseases, and type 1 diabetes (T1D).
SAB Biotherapeutics	SAB-142	ATG to slow the progression of T1D	Phase 1	Positive phase 1 results announced in January 2025; FDA cleared investigational new drug (IND) application for phase 1 trial in May 2024. In November 2023, SAB Biotherapeutics announced the completion of $67.1 million fund for its lead T1D immunotherapy candidate, SAB-142 (an anti-thymocyte globulin) to advance into clinical trials. Previously, in October 2023, SAB Biotherapeutics announced a security purchase agreement to raise up to $130 million for its lead T1D immunotherapy candidate, SAB-142 (an anti-thymocyte globulin).
Immutep	IMP761	LAG-3 agonist antibody as immunosuppression for autoimmune diseases	Phase 1	Immutep announced a positive phase 1 single ascending dose (SAD) trial update of IMP761 in healthy adults in December 2025
Repertoire	Multiple Shared Class II	Epitope target	Preclinical	On April 29, 2024, Bristol Myers Squibb and Repertoire Immune Medicines entered a partnership for up to $1.8 billion to advance vaccines for up to three autoimmune diseases. Repertoire is investigating a multiple shared HLA Class II epitope target in phase 1 as a T1D candidate in its tolerizing vaccine pipeline. This R&D is powered by the company's DECODE platform, which facilitates selection of disease-relevant epitopes across patients.

Other

Organization	Name	Type	Status	Timeline
Jaeb Center for Health Research, JDRF, University of Minnestoa	Verapamil	Calcium-channel blocker	Phase 3	Verapamil has shown beta cell preservation in adults and children with new-onset T1D. VER-A-T1D completed in April 2025; additional trials like MELD-ATG and WAVE T1D testing it alone and in combination (e.g., with ATG, teplizumab). At ADA 2025, poster 1849-P reported verapamil

				inhibits vascular adhesion molecules in islets. Preclinical comparisons show newer TXNIP inhibitors like TIX100 may be more potent. CLVer trial results, presented at ATTD 2023 and published in *JAMA*, show that stimulated C-peptide levels in the verapamil group (n=47) were 30% higher compared to placebo (n=41) at 52 weeks (p=0.04), showing that verapamil had partially preserved beta cell function. A phase 2 study published in *Nature Medicine* in 2018 reported that once daily oral verapamil promoted endogenous beta cell function while reducing insulin requirements and hypoglycemia in adults with recent-onset T1D; C-peptide levels in the verapamil group (n=11) were 35% higher compared to placebo (n=13) after 12 months. Verapamil was first approved in 1981, and is indicated for hypertension, chronic stable angina, unstable angina, supraventricular tachycardia, and paroxysmal supraventricular tachycardia.
Biomea Fusion	Icovamenib (BMF-219)	Oral menin inhibitor	Phase 2	Full 52-week results of COVALENT-111 trial expected in 2H25; topline results announced in December 2024 following data released at ATTD 2024 and WCIRDC 2023. Phase 2 COVALENT-112 trial in T1D open-label results expected 2H25; Preliminary data from first two patients announced in April 2024shows improvement in C-peptide levels after four weeks of dosing; FDA clearance of IND application for BMF-219 in T1D announced in October 2023.
PolTREG	PTG-007	Treg cell therapy	Phase 2/3	In July 2025, announced positive feedback from the FDA following a pre-IND meeting, with plans to apply for Fast Track Breakthrough or RMAT designation within the IND filing . The study may also be considered registrational, potentially expediting U.S. approval. In September 2024, announced positive results showing clinical remission and insulin independence in some patients for up to 12 years; Phase 2 trials to launch in 2H24.
TIXiMED	TIX100	Oral TXNP inhibitor	Phase 1	TIX100 demonstrates safety and tolerability in SAD trial in May 2025, advancing to multiple MAD trials; first cohort of phase 1 SAD trial completed dosing in February 2025 with no adverse events reported; Received IND approval for T1D and T2D in August 2024.
EVOQ Therapeutics	NanoDisc platform	Targeted antigen delivery to establish immune	Preclinical	EVOQ Therapeutics and JDRF entered a collaboration in December 2022; EVOQ's NanoDisc platform delivers antigens to dendritic cells in lymph nodes to establish a state of immune tolerance that protects pancreatic islets from

		tolerance and protect islets		immune destruction.
Genprex		Macrophage transformation to reduce autoimmune activity	Preclinical	Genprex advances partnership with the University of Pittsburgh, including exclusive license agreement for multiple technologies for development of gene therapy for T1D and T2D in Februrary 2025; Genprex and University of Pittsburgh expand partnership inDecember 2022; Follows February 2020 licensing agreement with the University of Pittsburgh for GPX-002 AAV gene therapy.
Kriya Therapeutics	KT-A112	AAV	Preclinical	Closed $270 million Series C in May 2022; closed $100 million Series B with help from T1D Fund in July 2021; Adeno-associated viruses (AAVs) are non-pathogenic viruses engineered to deliver DNA to drive the endogenous production of insulin.
Amarna and NorthX Biologics	Nimvec AM510	Gene therapy	Preclinical	Announces formal agreement in July 2025 to advance Nimvec AM510 gene therapy for T1D.

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