JULY 28, 2022

BT-001 Pivotal Clinical Trial Results

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Pioneering Prescription Digital Therapeutics for Cardiometabolic Diseases

BT-001 Pivotal Trial:
Statistically significant & clinically meaningful results in diverse patient population with advanced T2D

Primary Endpoint assessed at 90 days showed significant decrease in A1c as compared to control group receiving standard of care ($p<0.0001$)

Secondary Endpoint assessed at 180 days demonstrated sustained and improved response ($p=0.01$) Half of patients in BT arm achieved clinically meaningful changes with mean A1c reduction of 1.3% (SD 0.8%) in this subgroup

Robust safety data, with significantly fewer safety events in BT arm ($p<0.001$)

BT-001 use associated with **multiple additional cardiometabolic benefits**

Diverse & advanced patient population and unique trial design were setting a **high bar for success**

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Using Software Instead of Drugs: Unique Benefits of Digital Therapeutics

Opportunity to address healthcare inequities and access– Digital therapeutics can reach patients where they are and connect them to the best care despite the many barriers patients experience

Real-time insights into use and efficacy enables continuous improvement promising the potential for increasingly better efficacy without increased risk

Data generated offers greater insights enabling **better care and novel pricing models**

Potential to improve a broad range of health measures bears the promise to change - at scale - the course of a disease with **better overall long-term health outcomes and lower cost of care**

Development requires substantially less time and investment, enabling faster and more cost-efficient expansion into other potential indications or therapeutic areas

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Next Generation Therapeutics: The Better Therapeutics Approach

Developing Digital Therapeutics that are cleared by the FDA for a specific indication and have labeled claims. If cleared, patients obtain access through a physician prescription that is reimbursed via health insurance

Initially focused on cardiometabolic diseases, which rank among the most common and costly chronic conditions that share lifestyle behaviors as a common root cause

Advancing principles of Cognitive Behavioral Therapy (CBT), a well proven, validated approach to improve behavior by developing a novel CBT protocol and making it digitally available to improve access and scalability

Rigorous product development incorporating patient & provider feedback into thoughtfully designed randomized controlled studies, backed up by Real World Evidence studies to support payer negotiations

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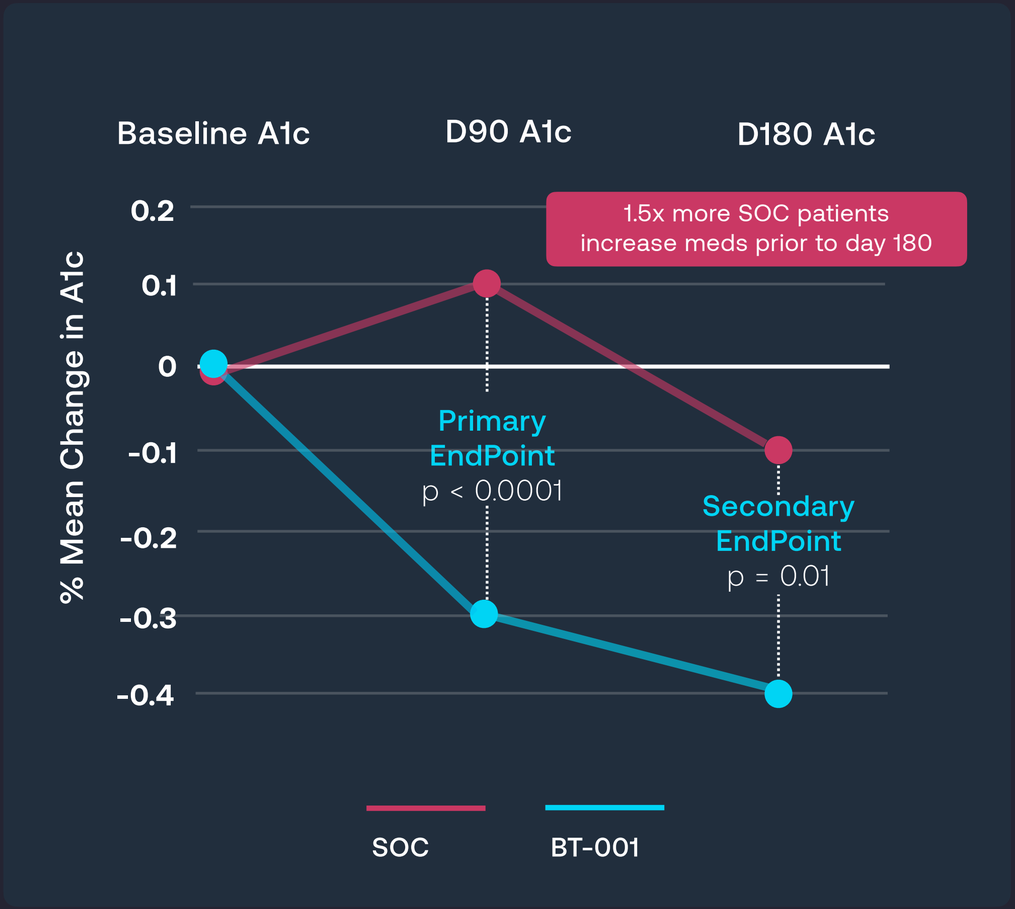
BT-001 Pivotal Trial Results



BT-001 demonstrated sustained and improved response at 180 days, with absolute A1c reduction advancing from 0.3% to 0.4%, highlighting potential for long-term improvements

- Both primary (A1c between group delta -0.4%, p<0.0001) and secondary endpoint (A1c delta -0.3%, p=0.01) were met
- Half of patients in BT arm achieved achieved clinically meaningful changes with absolute mean A1c reduction of 1.3% (SD 0.8%) in this subgroup

Robust safety data, with significantly fewer Adverse Events in BT arm (p<0.001)

BT-001 use associated with multiple additional cardiometabolic benefits and lower medication and lower healthcare utilization

BT-001 Pivotal Trial designed primarily for FDA de novo authorization

Nationally representative, diverse patient population

Investigators mirror real-world prescribers

Robust study design employed to minimize bias and set high comparison bar:

- Control arm is Standard of Care (i.e. gold standard care), not just treatment as usual
- Medication use and adjustment by investigators was not limited; only prandial insulin was excluded
- Patients were not mandated nor incentivized to use BT-001; instead were free to self-select dose

Nationally representative, diverse patient population recruited

Patient population recruited from 6 States, includes groups underrepresented in clinical trials, with historically poor access to care

Parameter / Category	Statistic	Standard of Care (n=343)	BT-001 (n=325)
Age (yrs)	Mean	58.1	58.0
% Female	%	56.3%	56.0%
Race	%		
White		61.2%	62.2%
Black or African American		29.2%	29.5%
Asian		5.2%	5.2%
American Indian or Alaskan Native		1.7%	1.2%
Native Hawaiian or Other Pacific Islander		0.6	0.3%
Ethnicity - Hispanic or Latino	%	14.0%	17.2%
Median Household Income by ZIP Code	Mean	$67,737	$69,789
% High School Degree or Some College but no Degree	%	42.0%	38.2%

Canonico, Mario Enrico, et al. "Cognitive behavioral therapy delivered via digital mobile application for the treatment of type 2 diabetes: Rationale, design, and baseline characteristics of a randomized, controlled trial." *Clinical Cardiology (2022).*

Participants had long-standing T2 diabetes, high cardiovascular risk, multiple comorbidities and extensive medication use

Parameter / Category	Statistic	Standard of Care (n=343)	BT-001 (n=326)
BMI (kg/m^2)	Mean	34.7	34.6
Baseline HbA1c (%)	Mean	8.1%	8.2%
Years Since Diagnosis	Mean	10.9	11.0
% on 2 or More Antihyperglycemic Medications	%	67.5%	68.4%
Using Antihypertensive Medications	%	71.7%	67.1%
% on 2 or More Number of Antihypertensive Medications [1]	%	66.5%	69.0%
10 Year CV Risk Score	Mean	15.1%	15.1%
Number of Comorbidities	Mean	2.7	2.8

[1] For those treated for hypertension (67.5% of participants)

Canonico, Mario Enrico, et al. "Cognitive behavioral therapy delivered via digital mobile application for the treatment of type 2 diabetes: Rationale, design, and baseline characteristics of a randomized, controlled trial." *Clinical Cardiology (2022).*

Baseline diabetes medications reveal robust background therapy compared with general diabetes population

Medication Class	General Diabetes Population (2018) [1]	SOC	BT-001
All	82.7%	96.5%	96.0%
Metformin	59.5%	79.9%	80.1%
Sulfonylureas	24.4%	34.4%	36.2%
SGLT2 inhibitors	< 7.1%	24.8%	21.8%
GLP-1 analogues	< 7.1%	24.8%	19.0%
Insulin	25.6%	19.5%	17.8%
DPP-4 Inhibitors	10.8%	13.7%	17.2%
Thiazolidinediones	3.3%	5.0%	5.5%
Meglitinides	-	0.3%	0.9%

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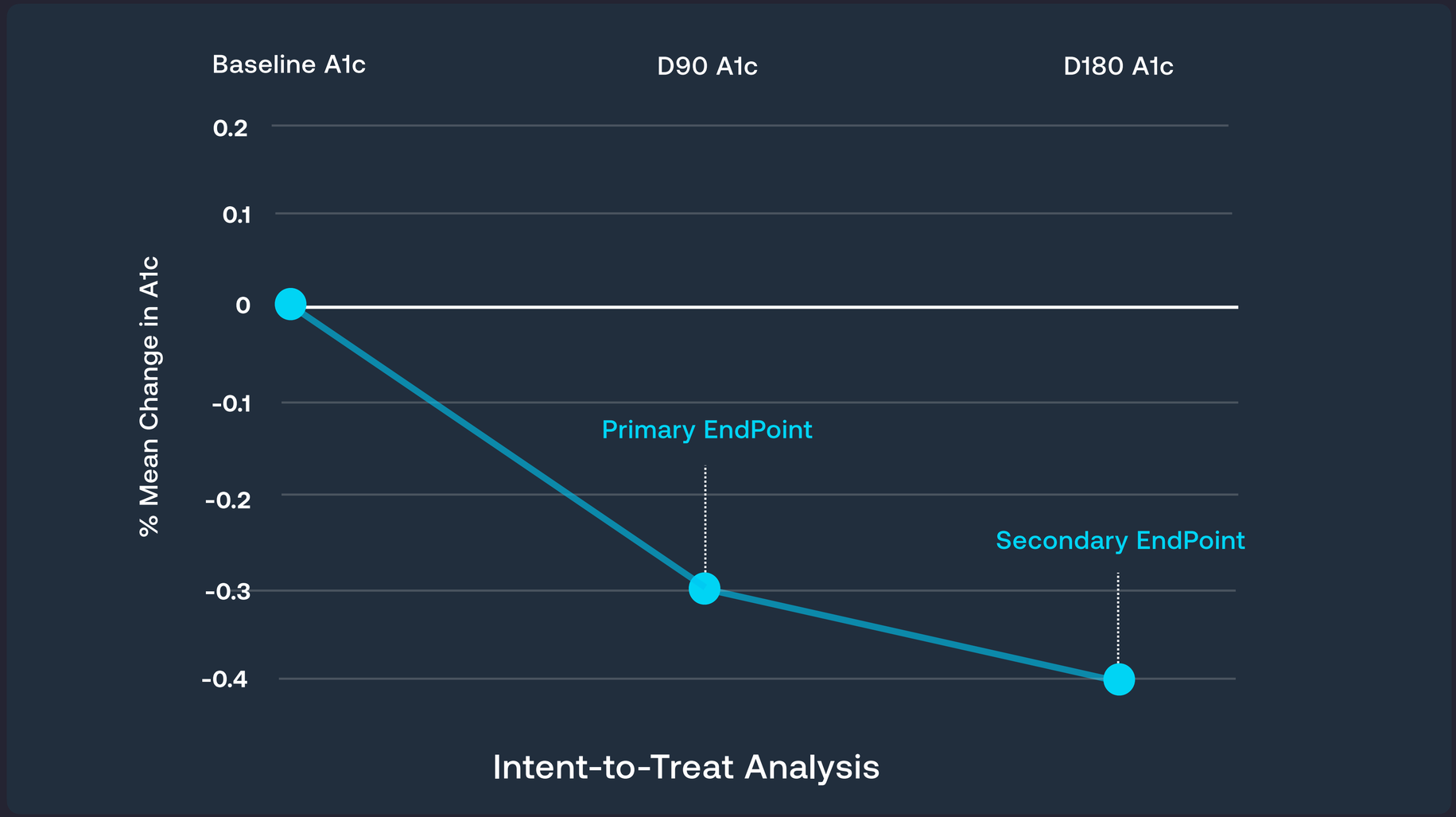
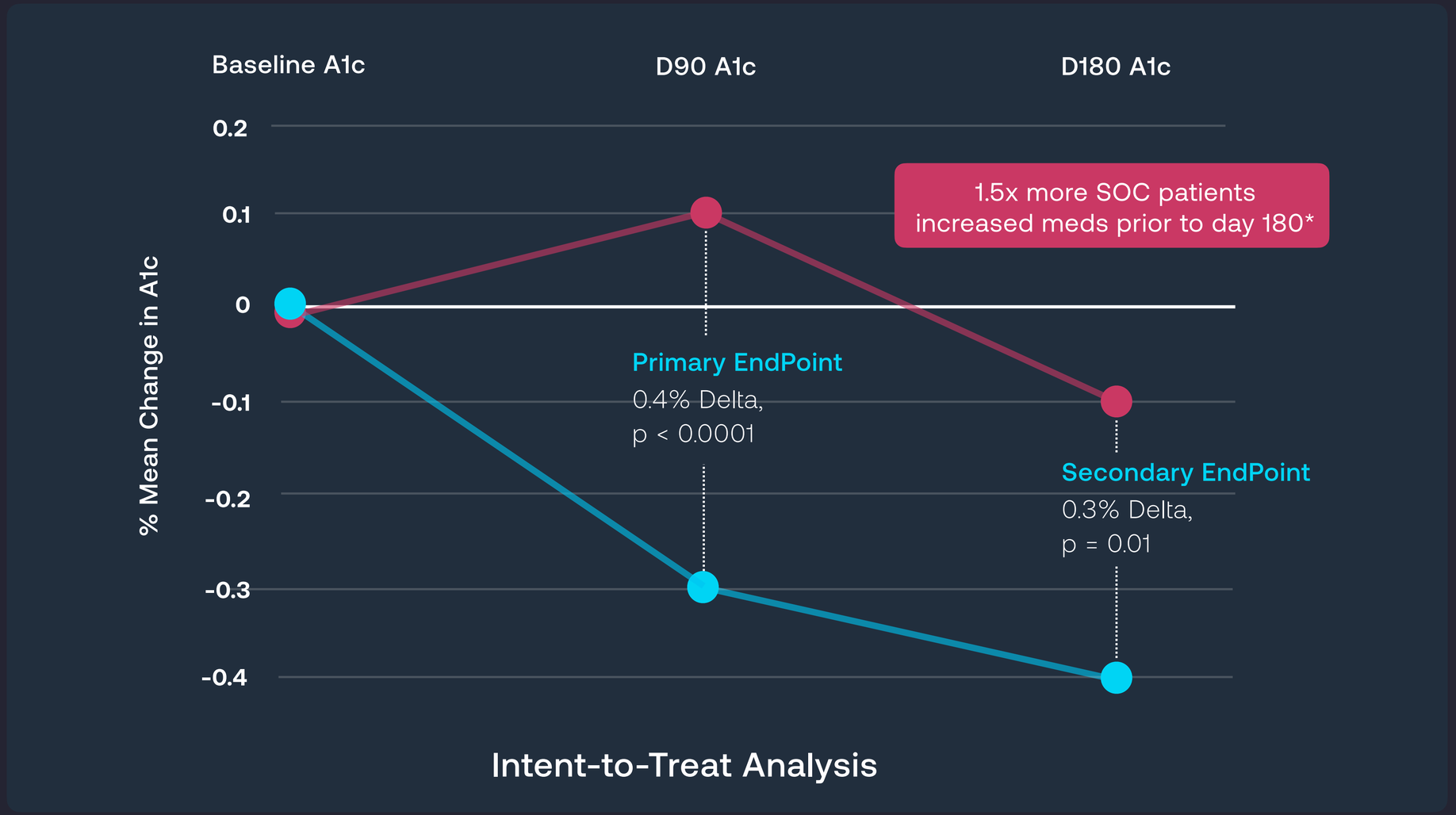
[1] Fang et al. Trends in Diabetes Treatment and Control in U.S. Adults, 1999-2018. *N Engl J Med* 2021;384:2219-28. DOI: 10.1056/NEJMsa2032271

BT-001 produced clinically meaningful and sustained reduction in A1c



BT-001 reduced A1c despite on-study addition of more diabetes medication in the Standard of Care control group



** Prior to D180 A1c, comparable % of patients reduced antihyperglycemic medications (5.5% SOC; 4.3% BT-001)*

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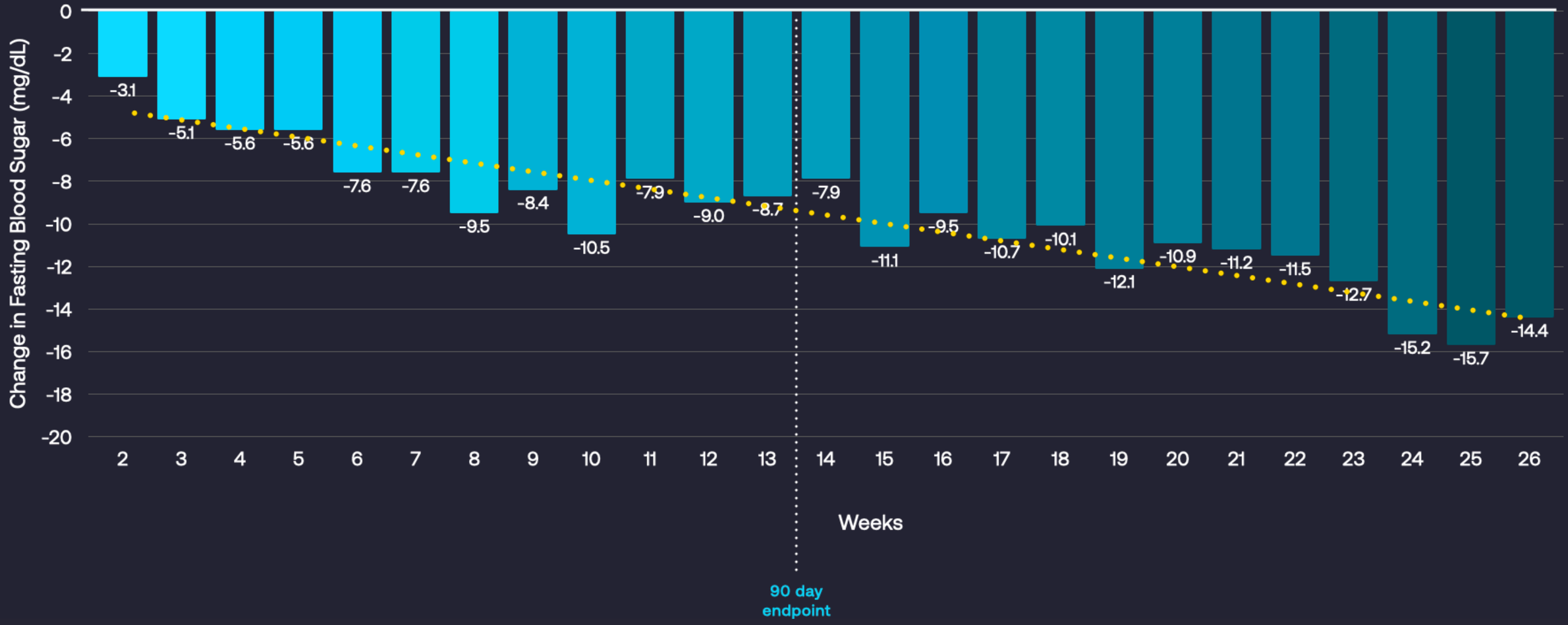
Trending average change in fasting blood glucose shows gradual and steady improvements, with no clear peak



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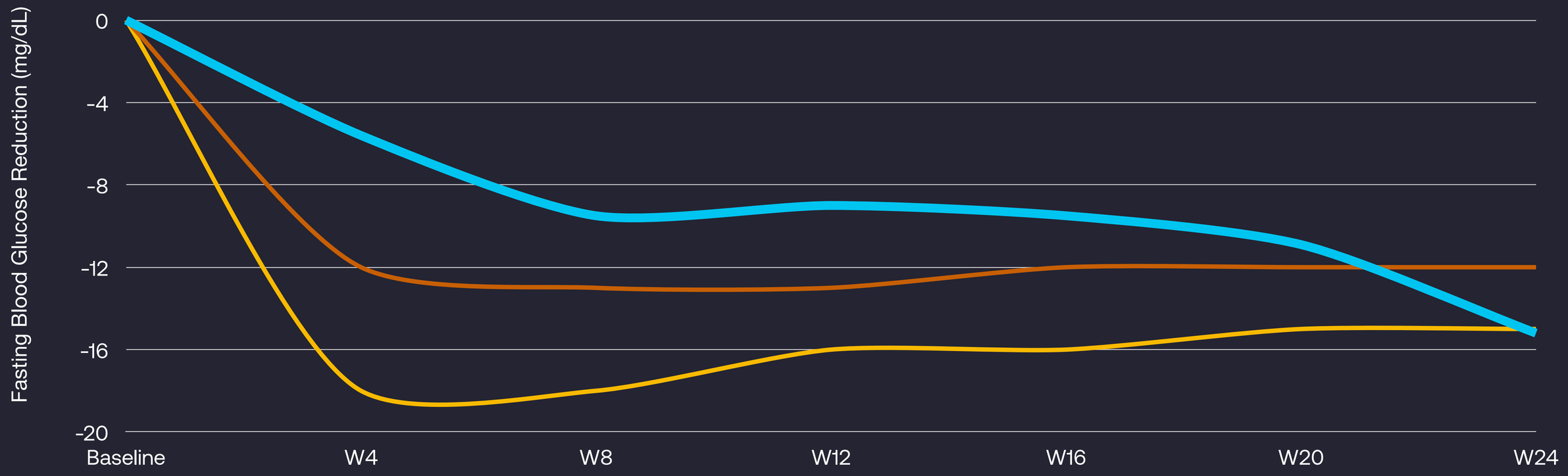
Trends in fasting blood glucose in different therapies



Ferrannini E et al. Dapagliflozin monotherapy in type 2 diabetic patients with inadequate glycemic control by diet and exercise: a randomized, double-blind, placebo-controlled, phase 3 trial. *Diabetes Care.* 2010;33:2217-2224.

Goldstein BJ, et al; for Sitagliptin 036 Study Group. Effect of initial combination therapy with sitagliptin, a dipeptidyl peptidase-4 inhibitor, and metformin on glycemic control in patients with type 2 diabetes. *Diabetes Care*. 2007;30(8):1979–1987.

Note: These results are from different studies with different trial designs and patient populations. No head-to-head studies between these candidates have been conducted.

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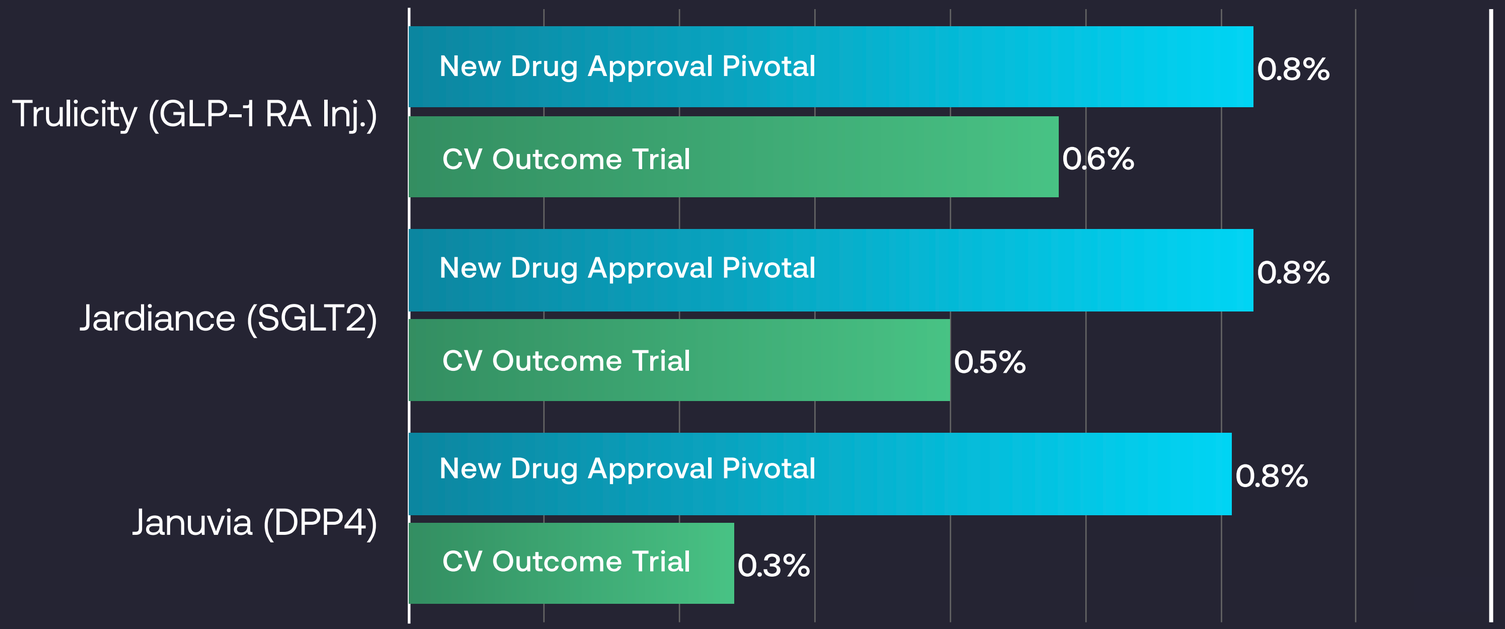
Cardiovascular Outcome Trials (CVOTs) show lower relative A1c reduction compared with new drug pivotal for same drug



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Umpierrez et al; Efficacy and Safety of Dulaglutide Monotherapy Versus Metformin in Type 2 Diabetes in a Randomized Controlled Trial (AWARD-3) *Diabetes Care* 2014;37(8):2168–2176.

Jardiance- Zinman B, et al. "Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes". The New England Journal of Medicine. 2015. 373(22):2117-28.

Roden M et al; on behalf of the EMPA-REG MONO trial investigators. Empagliflozin monotherapy with sitagliptin as an active comparator in patients with type 2 diabetes mellitus: a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Diabetes Endocrinol. 2013;1(3):208–19.

Januvia- Green JB, et al. "Effect of sitagliptin on cardiovascular outcomes in type 2 diabetes". *The New England Journal of Medicine*. 2015. 373(3):232-242.

Aschner P, et al; Sitagliptin Study 021 Group. Effect of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy on glycemic control in patients with type 2 diabetes. Diabetes Care. 2006 Dec;29(12):2632-7.

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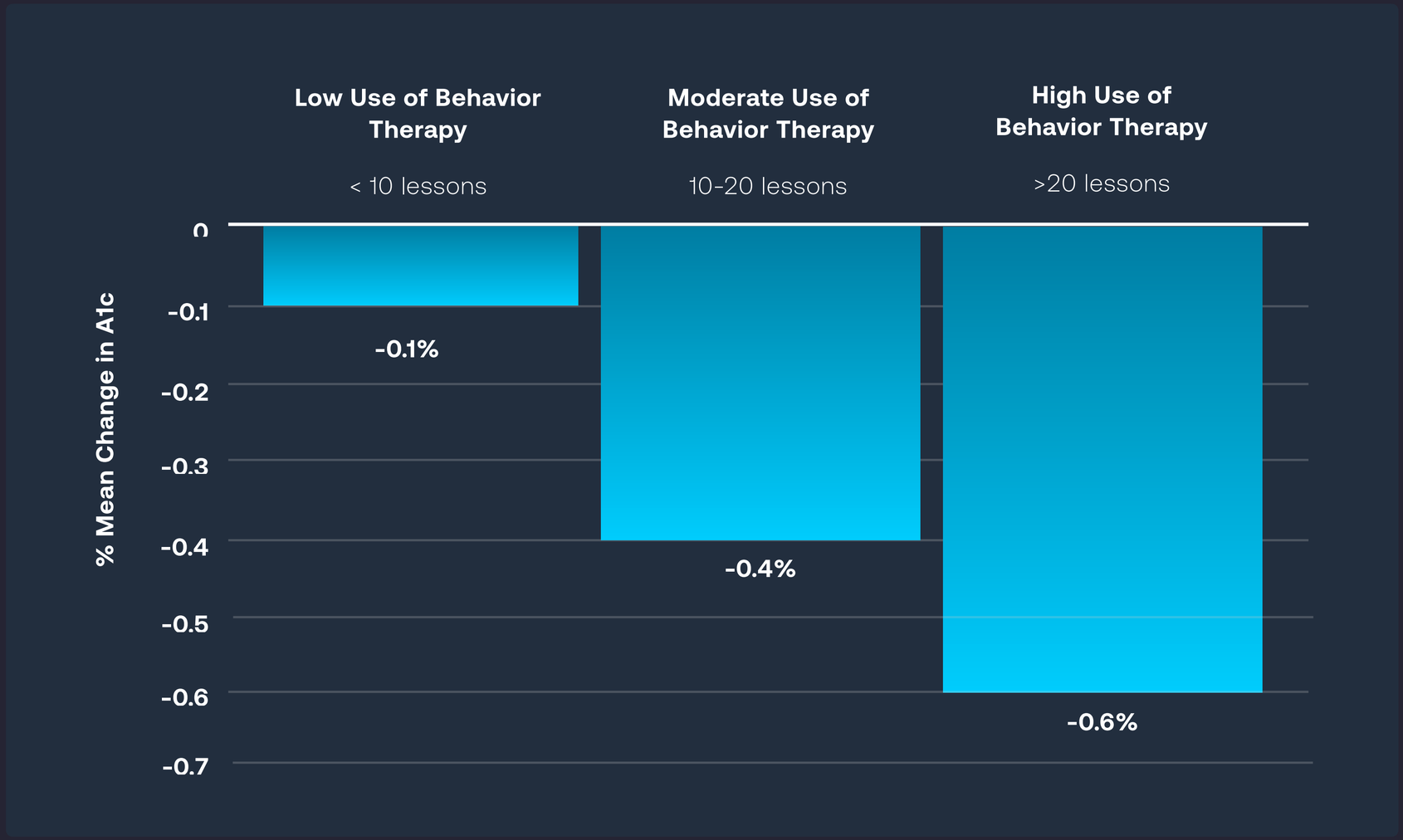
Trial design may influence A1c reduction observed. BT-001 pivotal trial design is more similar to diabetes cardiovascular outcome trials

Trial Characteristic	New Drug Pivotal	CV Outcome Trial	BT-001 Pivotal
Poorly Controlled Diabetes at Baseline	Yes	Yes	Yes
Diabetes Disease Duration (mean)	< 10 yrs	> 10 yrs	> 10 yrs
Baseline Therapy Limited	Highly (e.g. Metformin monotherapy)	Moderately (e.g. Max of 2 drugs at Baseline)	Minimally (Only Prandial Insulin excluded)
Comparison Arm	Placebo or Single Agent	Standard of Care	Standard of Care
Dosage of Investigational Therapy Controlled	Yes	Yes	No

Patients who used BT-001 more had greater reduction in A1c

Participants self-selected dose of nCBT. Higher dose of nCBT lessons completed associated with larger A1c improvements at 180 days



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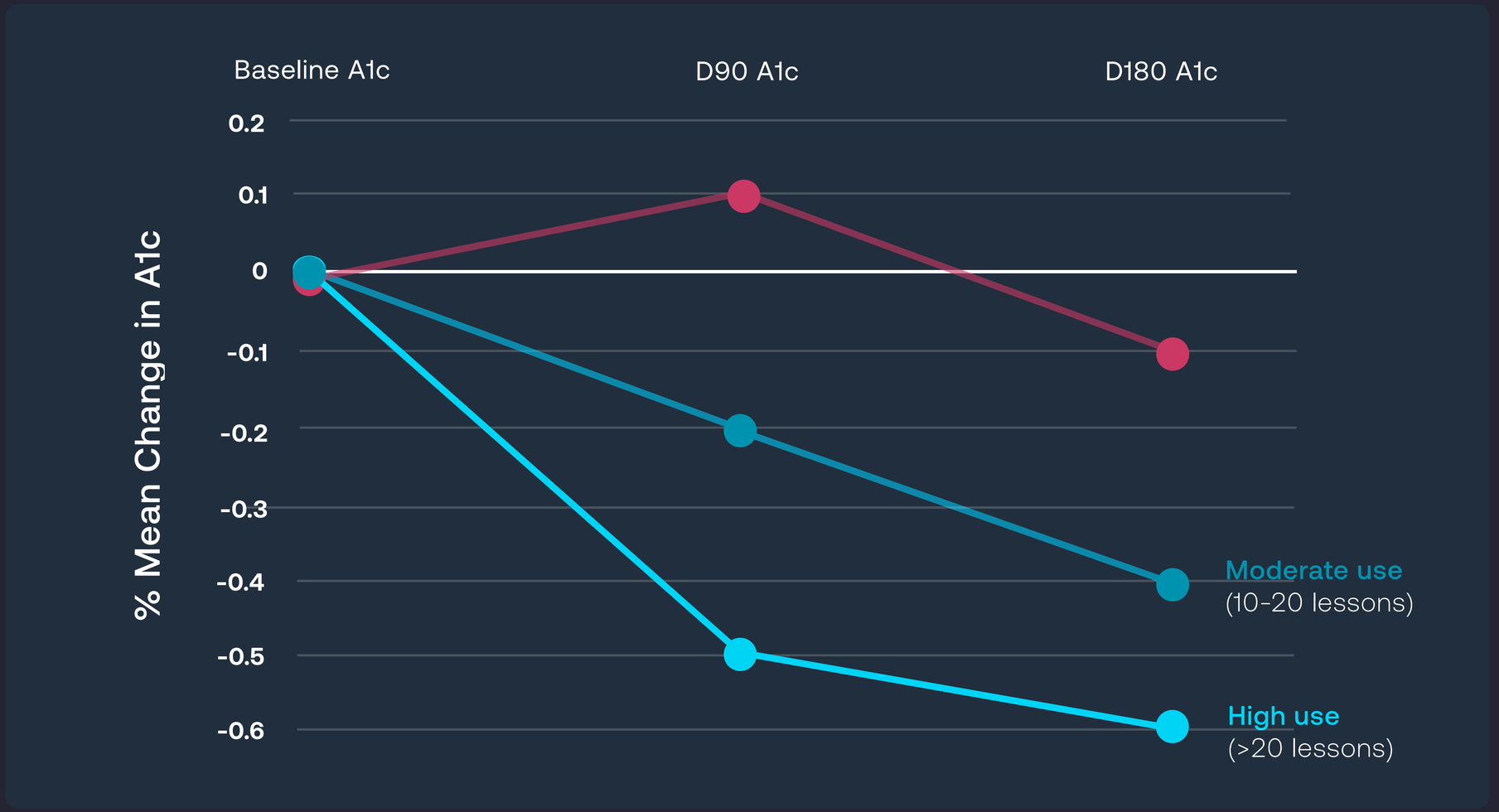
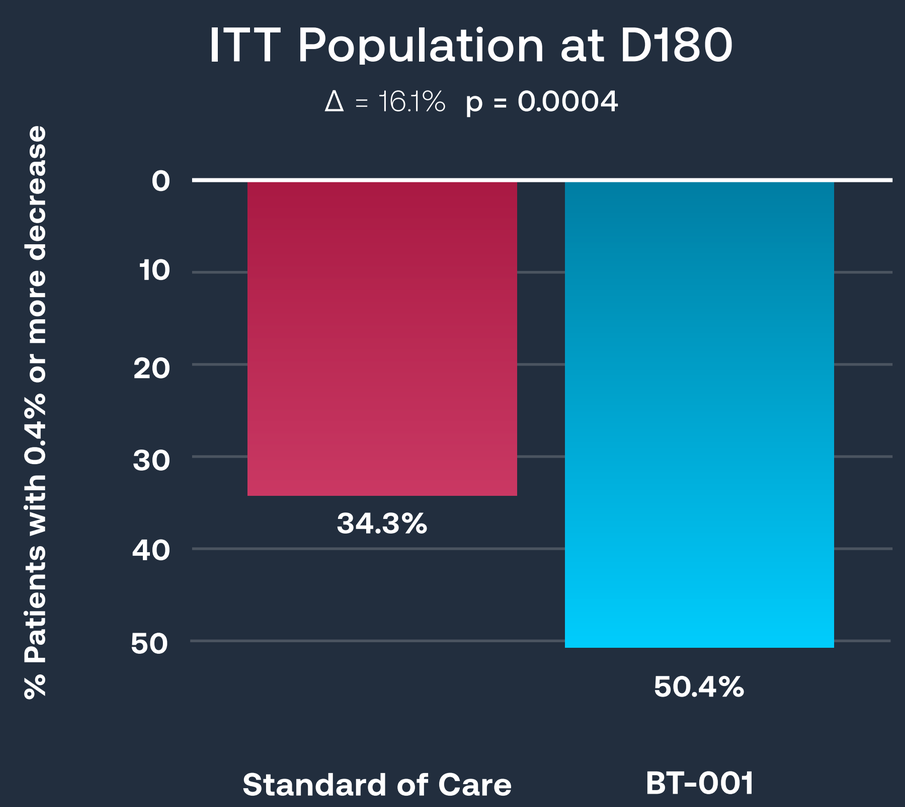
Higher dose subgroup shows substantially greater A1c improvement compared to Standard of Care control group



1.5x more BT-001 patients achieved meaningful A1c change

Significant improvements observed in BT-001 Group despite use of fewer diabetes medications

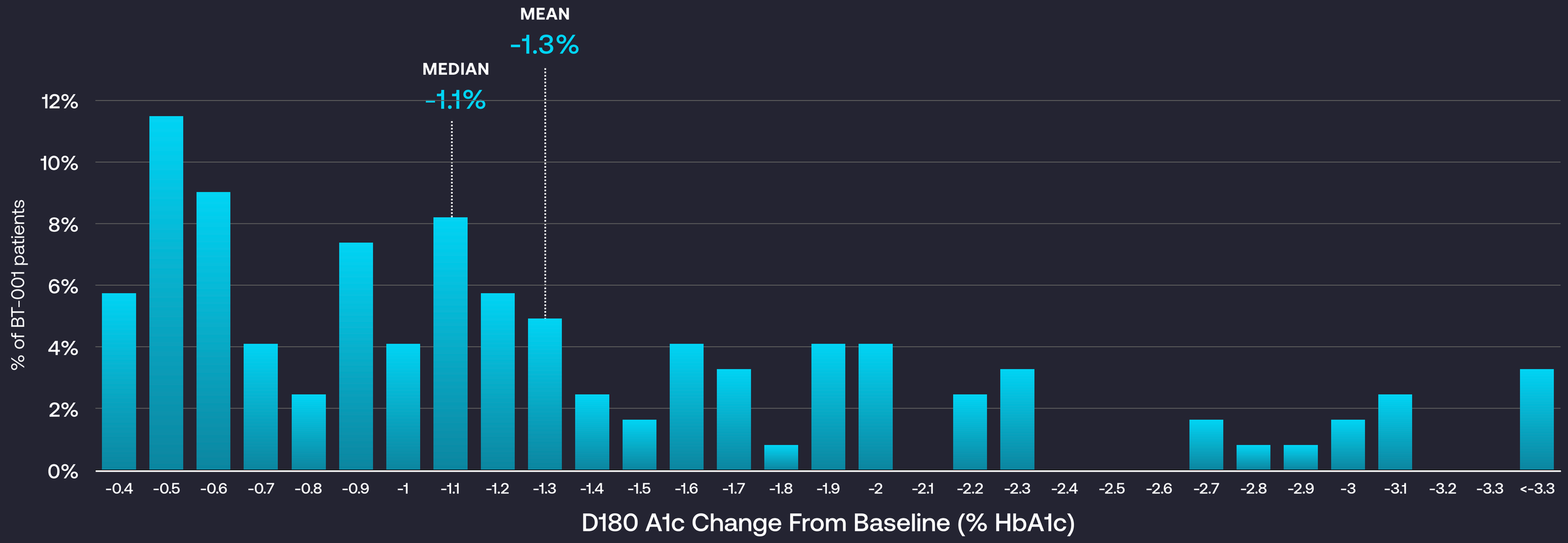


30 % Achieve 1% or more A1c reduction (vs 17%, p=0.001)

30 % Achieve blood sugar control target of A1c < 7% (vs 20% SOC, p=0.009)

BT-001 Meaningful Responders show range of large improvements at 180 days

"Meaningful Responders" defined as 0.4% or more A1c improvement



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180 Day safety data reveals significantly fewer Adverse Events

BT-001 patients had statistically significant fewer AEs and Serious AEs

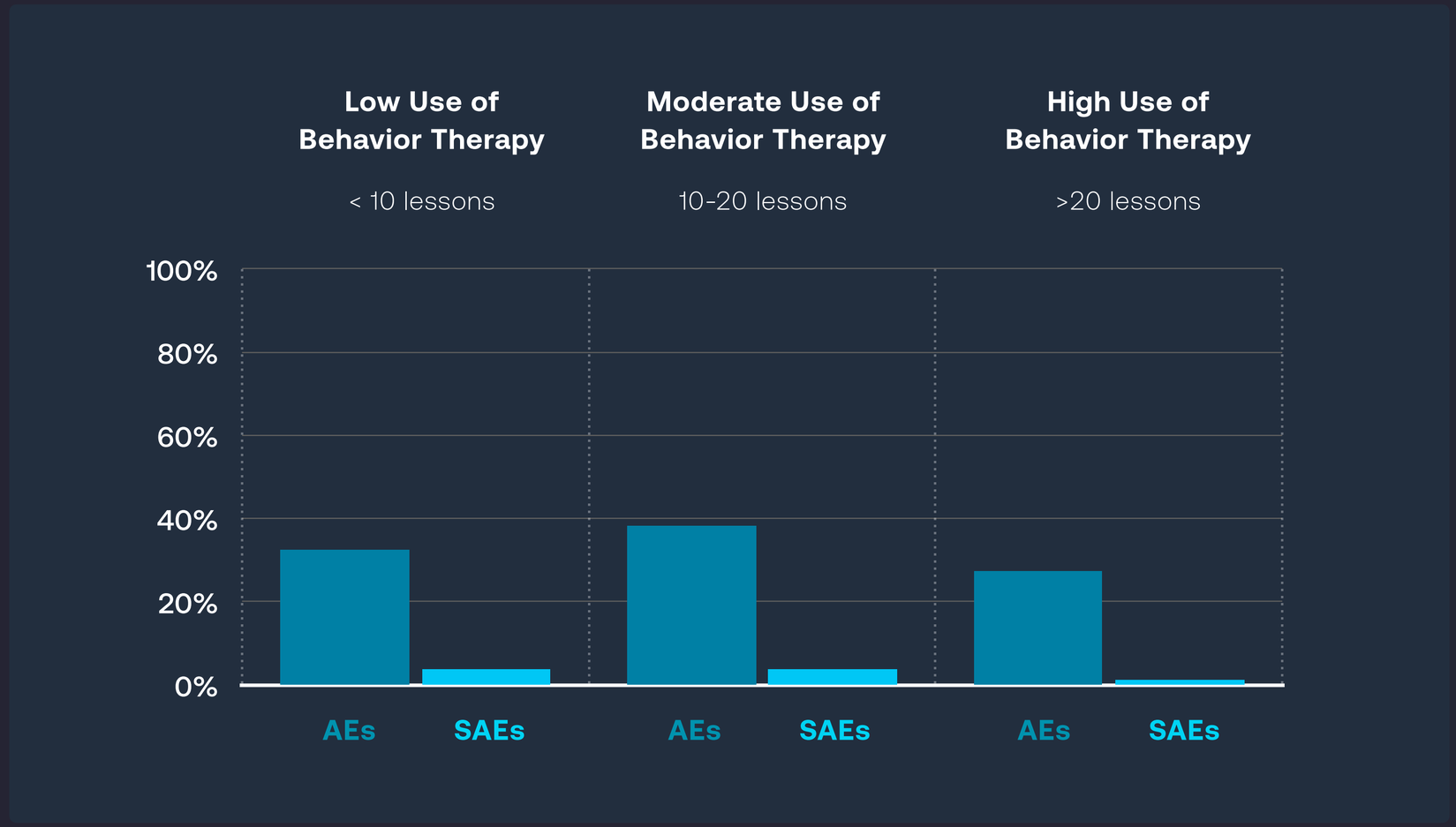
Number of subjects who experienced:	Standard of Care (n=343) Subjects n (%)	Standard of Care (n=343) Events n	BT-001 (n=325) Subjects n (%)	BT-001 (n=325) Events n	
An Adverse Event (AE)	188 (54.8%)	324	135 (41.5%)	265	p < 0.001
A Serious Adverse Event	24 (7.0%)	26	9 (2.8%)	9	p = 0.01
An AE Possibly/Probably Related to Study Intervention	0 (0.0%)	0	3 (0.9%)	4	
An AE that is Related to Medical Software	0 (0.0%)	0	0 (0.0%)	0	

BT-001 patients avoided more Serious Adverse Events (SAEs) commonly found in T2 diabetes

Number of subjects who experienced:	Standard of Care (n=343)		BT-001 (n=325)	
	Subjects n (%)	Events n	Subjects n (%)	Events n
A Serious Adverse Event (SAE)	24 (7.0%)	26	9 (2.8%)	9
SAEs Possibly Related to Diabetes / Cardiometabolic Health	14 (4.1%)	14	5 (1.5%)	5
Cardiovascular	6 (1.7%)	6	2 (0.6%)	2
Respiratory	2 (0.6%)	2	1 (0.3%)	1
Infectious	6 (1.7%)	6	2 (0.6%)	2
Other SAEs	12 (3.5%)	12	4 (1.5%)	4
Death	1 (0.3%)	1	0 (0.0%)	0

More Adverse Events (AEs and SAEs) are not observed with more use of BT-001

Participants self-selected dose. Higher dose associated with larger improvements, but not higher rates of AEs.



Safety profiles of top performing diabetes drugs differ from BT-001

Adverse Reaction (>/= 5%)	GLP1	SGLT2	BT-001 Pivotal
Nausea	**Yes**	No	No
Vomiting	**Yes**	No	No
Diarrhea	**Yes**	No	No
Abdominal pain	**Yes**	No	No
Constipation	**Yes**	No	No
Female genital mycotic infections	No	**Yes**	No
Urinary track infections	No	**Yes**	No
Devise related adverse events	N/A	N/A	< 1%

Note: These results are from different studies with different trial designs and patient populations. No head-to-head studies between these candidates have been conducted.

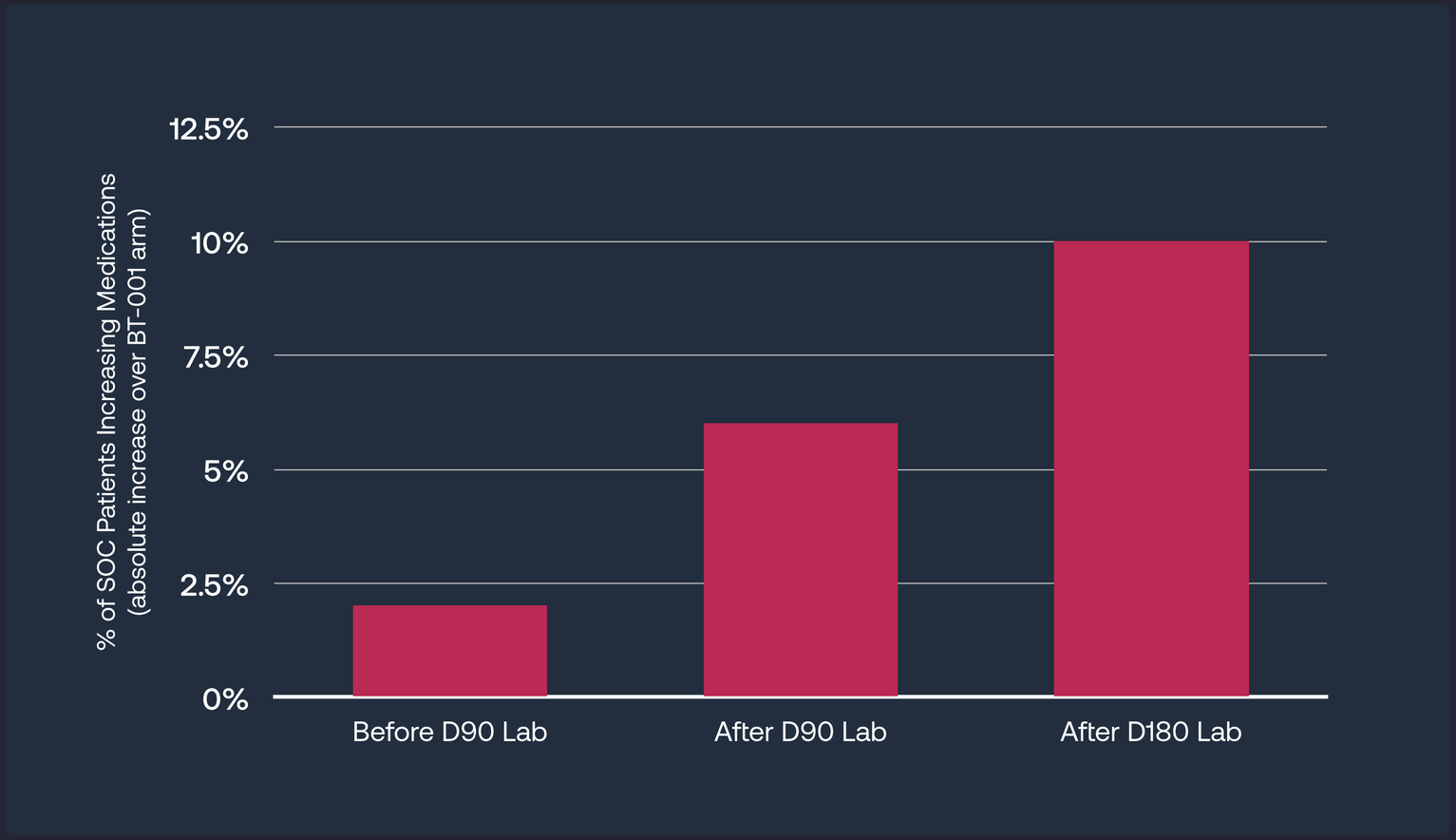
Data reveals statistically significant changes in multiple exploratory endpoints, underscoring potential for broad-based benefits

Statistically significant findings in:

- **Systolic Blood Pressure**
- **Weight Reduction**
- **Mood Scores**
- **Quality of Life Scores (Physical Health-Related)**
- **Adverse Event and Serious Adverse Event Rates**

Data to be submitted for peer-review publications.

Antihyperglycemic medication utilization and healthcare utilization increased more in Standard of Care control group patients with a widening gap over 6-months

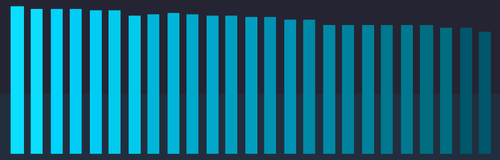


BT-001 patients experienced fewer hospitalizations, ER visits, and outpatient visits over length of study

During 180 days of use, patient engagement and persistence exceed benchmarks for consumer health & wellness apps*

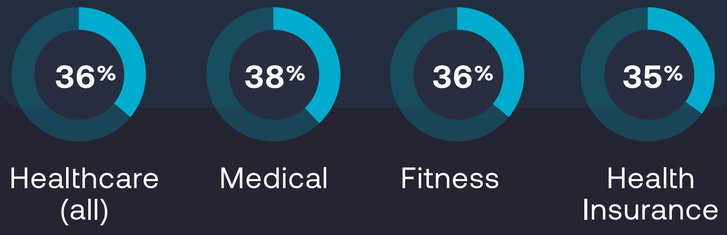
5.9

Average minutes / day spent in app



81%

Percentage of patients using the app at 180 days



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NPS Score after 180 days

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*Apptentive | 2022 Mobile Customer Engagement Benchmark Report - % retention at 90 days. *Retention was 94% in BT-001 group at 90 days*

Marc Bonaca, MD, MPH

Executive Director, CPC Clinical Research

Associate Professor of Medicine, Cardiology, and Vascular Medicine

Director of Vascular Research, University of Colorado School of Medicine

Addressing the unmet needs in Type 2 Diabetes requires new therapies

Qualities of an ideal new therapy in T2 Diabetes

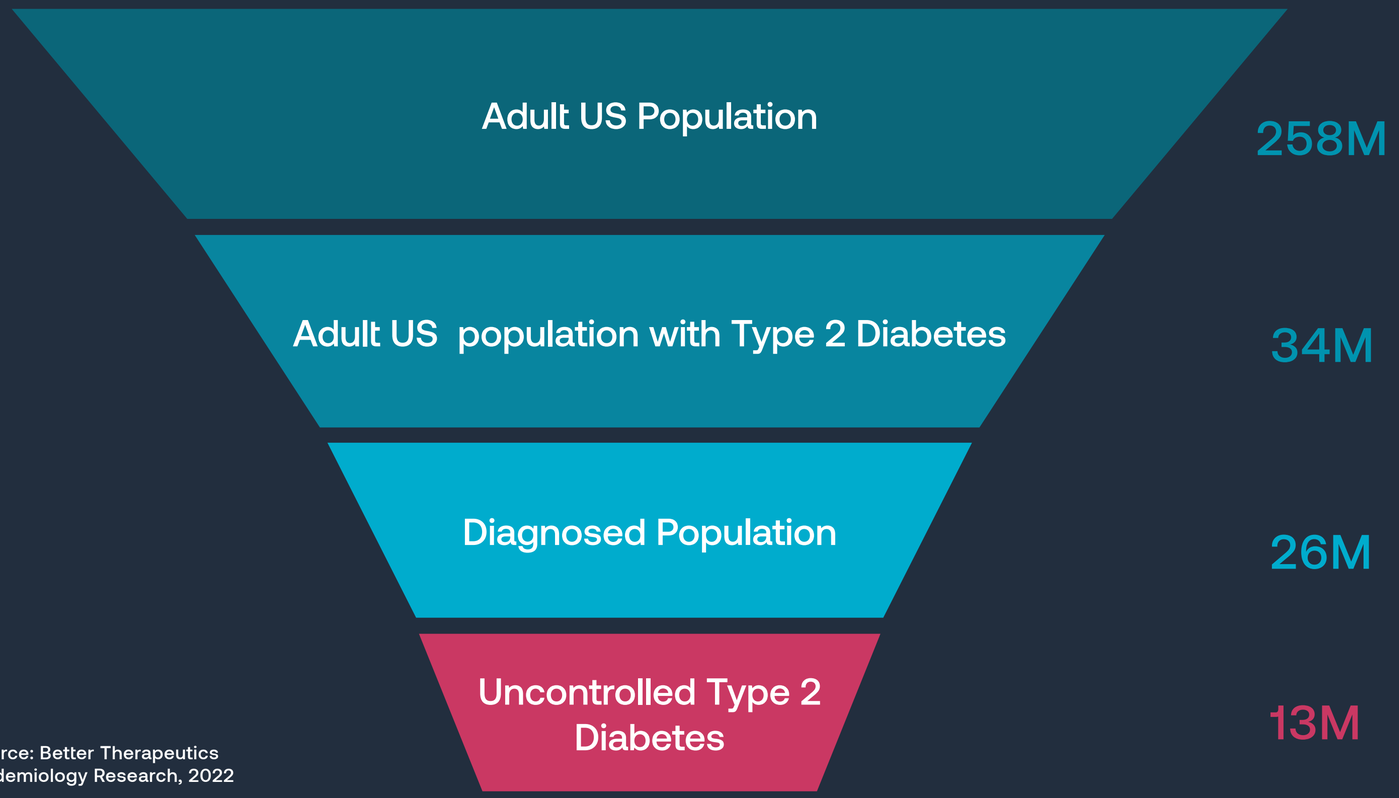
1. Non-pharmacologic
2. Can be prescribed and data tracked in medical record
3. Additive effects on top of evidence-based therapy
4. Potential to decrease need for medication and/or healthcare utilization
5. Safe
6. Sustained effect

Addressing the unmet needs in Type 2 Diabetes requires new therapies

Qualities of an ideal new therapy in T2 Diabetes

- Non-pharmacologic
- Can be prescribed and data tracked in medical record
- Additive effects on top of evidence-based therapy
- Potential to decrease need for medication and/or healthcare utilization
- Significantly fewer AEs and SAEs in BT-001 group
- Sustained and improved A1c reduction at 180 days

We intend to go to market with a focus on patients whose blood sugar remains uncontrolled despite the use of medications



Source: Better Therapeutics Epidemiology Research, 2022

COST IN 2020*

~$490B

COST IN 2030*

~$600B

*Source: Projected costs from Rowley et al, Diabetes 2030: Insights from Yesterday, Today and Future Trends. *Population Health Management* 2017; Vol 20,1:6-12

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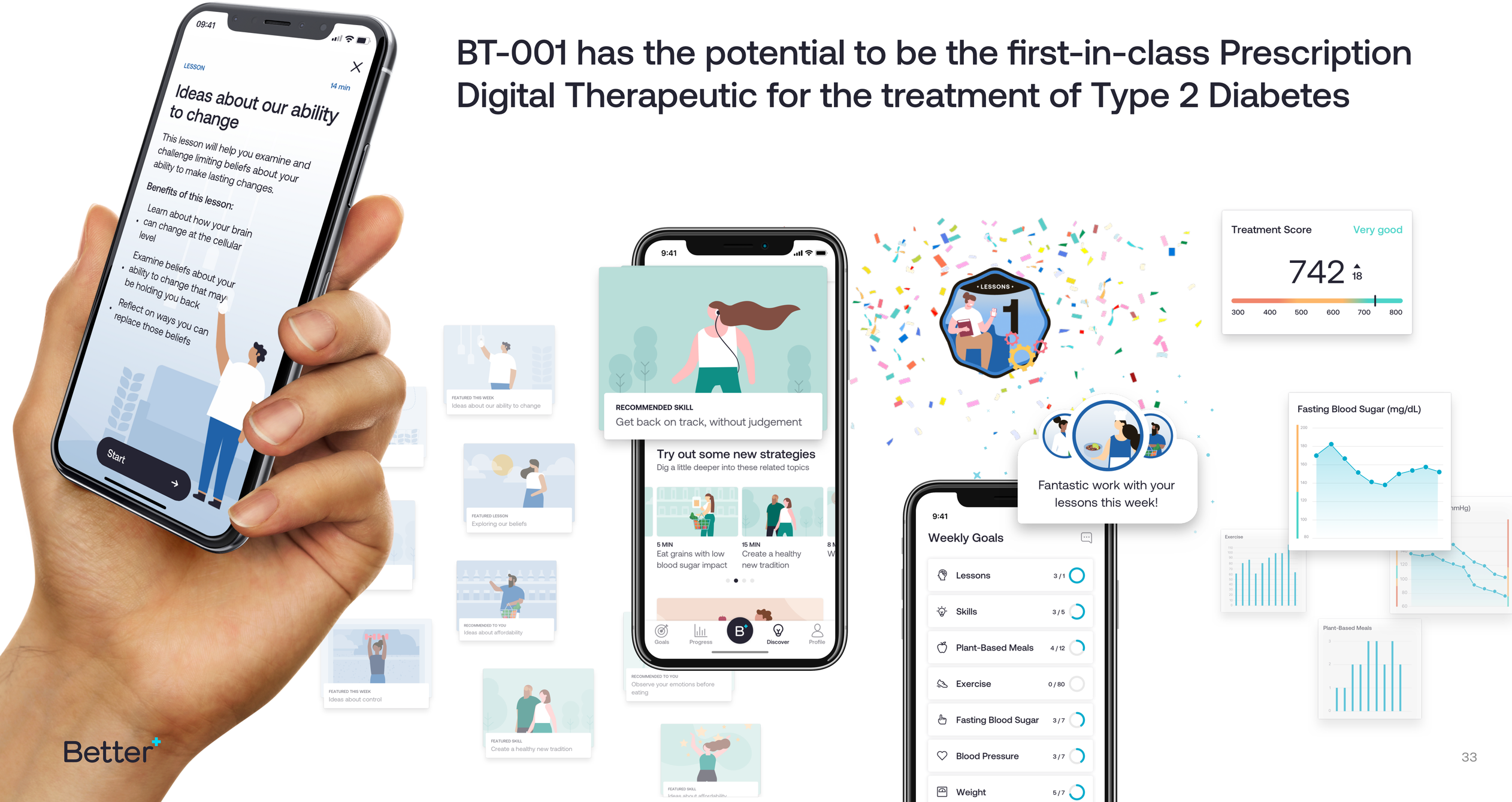
BT-001 has the potential to be the first-in-class Prescription Digital Therapeutic for the treatment of Type 2 Diabetes



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CPT Codes:

New for 2022/2023 CPT Editorial Panel accepted the use of temporary codes to identify supplying a device, reporting and interpretation of CBT applications.

0702T - Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days

0703T - Management services by physician or other qualified health care professional, per calendar month

Bipartisan Bill Introduced:

March 10, 2022 Reps. Mike Thompson (CA-05) and David McKinley (WV-01) and Sens. Jeanne Shaheen (D-NH) and Shelly Moore Capito (R-WV) introduced the bipartisan legislation, *Access to Prescription Digital Therapeutics Act of 2022*

HCPCS Code:

CMS established a new HCPCS code Level II Code A9291, effective April 1, 2022, for Prescription Digital Behavioral Therapy, FDA cleared, per course of treatment

We plan to focus on securing coverage from regionally dominant, early adopting commercial payers, IDNs/health systems

LEADING INDICATORS OF ADOPTION:

PAYERS

- Population health focused
- History of adopting new technologies

HEALTH SYSTEMS

- Centralized decision-making
- Accountable Care Organization (ACO) affiliations

Real-world evidence from randomized, controlled, multi-site program will inform our understanding of durability, impact on costs and medication use

	BT-001 Participants	Study Size	Duration
Mass General Brigham	500	750	18-month
CPC Clinical Research Ascension VA | U.S. Department of Veterans Affairs	250	500	24-month
Catalyst HEALTH NETWORK	250	250	12-month

Population: Participants with type 2 diabetes; A1c between 7.0% and 11.0%, not on prandial insulin

Design: Open-label, real world interventional studies using within participant comparison or control arm

Primary Measures: Mean change in A1c after 6 and 12-months (mean change within participant or compared to control)

Secondary Measures: Mean change in medication usage after 6 and 12-months (mean change within participant or compared to control)

Exploratory Endpoints: Changes in quality of life, diabetes treatment satisfaction, blood pressure, cholesterol, weight, lipids and HbA1c trends, medication use, diabetes related hospitalizations, emergency room visits, and outpatient visits at 12 months or more

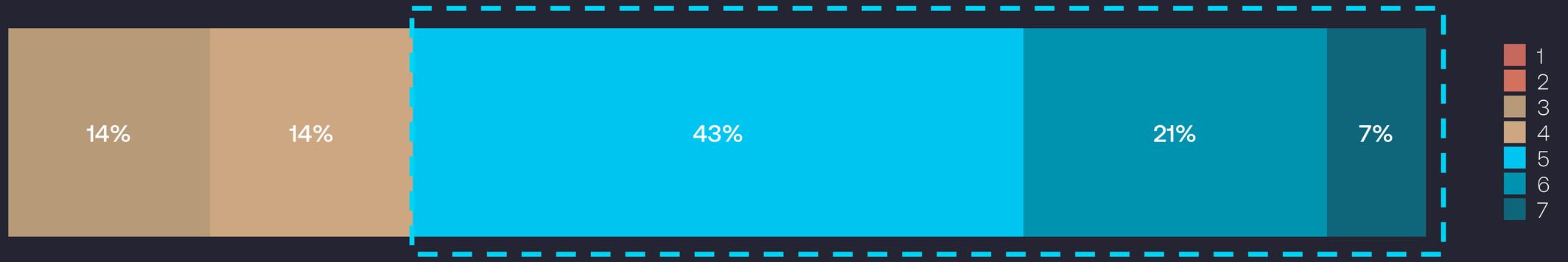
Payer Survey

National and regional payers, as well as PBMs reacted positively to BT-001's Target Product Profile

Likelihood to Cover BT-001

(n=14)

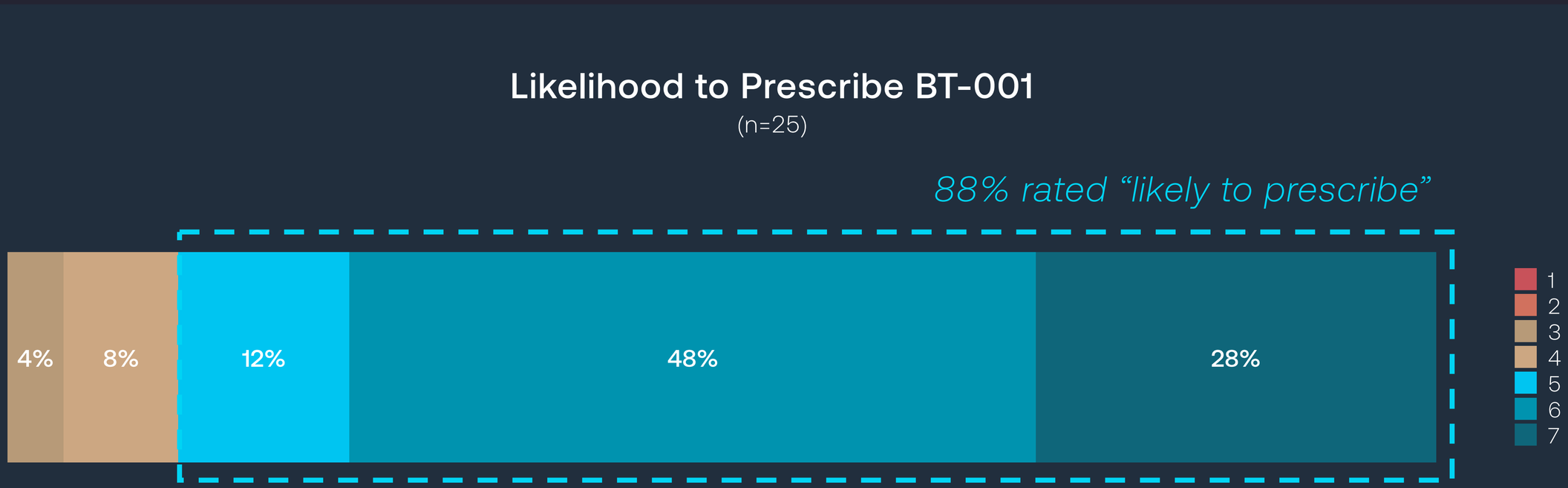
71% responded "likely to cover"



Source: Better Therapeutics Quantitative Market Research, June 2022. The 1 to 7 scale represents the likelihood of the payer to cover BT-001, where 1 was "not at all likely" and 7 was "extremely likely."

Provider Survey

Providers have expressed a willingness to prescribe BT-001 based on Target Product Profile



Source: Better Therapeutics Quantitative Market Research, Mar 2022. The 1 to 7 scale represents the likelihood of the provider to prescribe BT-001 to at least some of their patients, where 1 was “not at all likely” and 7 was “extremely likely.”

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Pioneering Prescription Digital Therapeutics for Cardiometabolic Diseases

Key Priorities

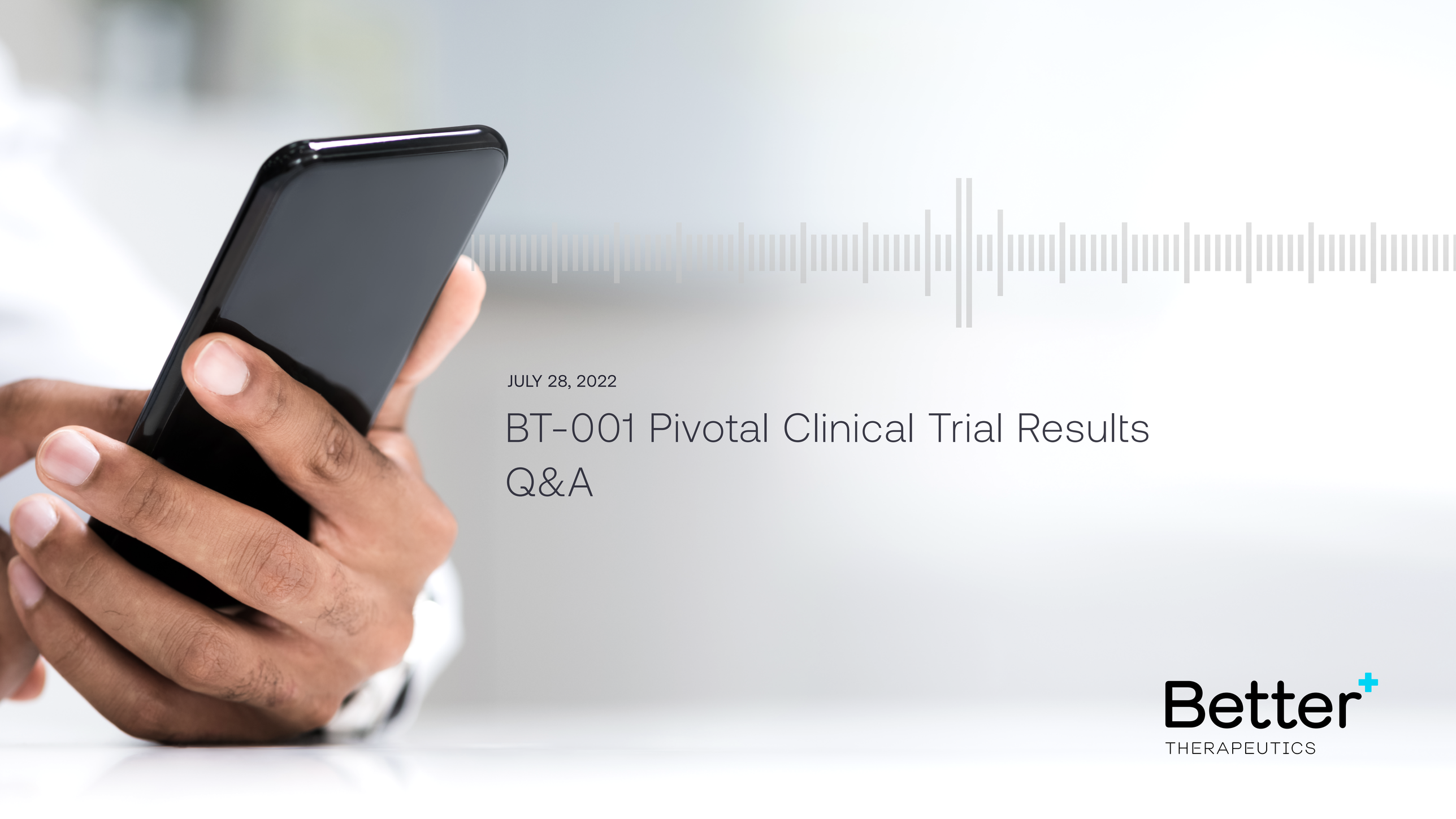
Financing – initiated a broad assessment of potential financing options to support our commercial launch and potentially expand into other cardiometabolic diseases.

De Novo Submission - Submit a de novo classification request with the FDA seeking marketing authorization of BT-001 for the treatment of patients with Type 2 diabetes in the third quarter of 2022.

Commercial Launch - Advance our preparations for the potential commercial launch of BT-001

Upcoming Milestones

Q3 2022	De Novo Submission
Q3 2022	Health economic model for BT-001 and payer coverage discussions
Q4 2022	Completion of LivVita Liver Study for NAFLD and NASH
Q4 2022/ Q1 2023	Address financing needs
Pending FDA Authorization	Commercial launch
2023	Pipeline Expansion / Next Pivotal Study



JULY 28, 2022

BT-001 Pivotal Clinical Trial Results Q&A

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