

Metabolic Changes at 48 Weeks in People With HIV and Virologic Suppression Switching to Single-Tablet Bictegravir/Lenacapavir From Complex Antiretroviral Regimens: Results From the Phase 3 ARTISTRY-1 Trial

TUPEB089ARTISTRY-1

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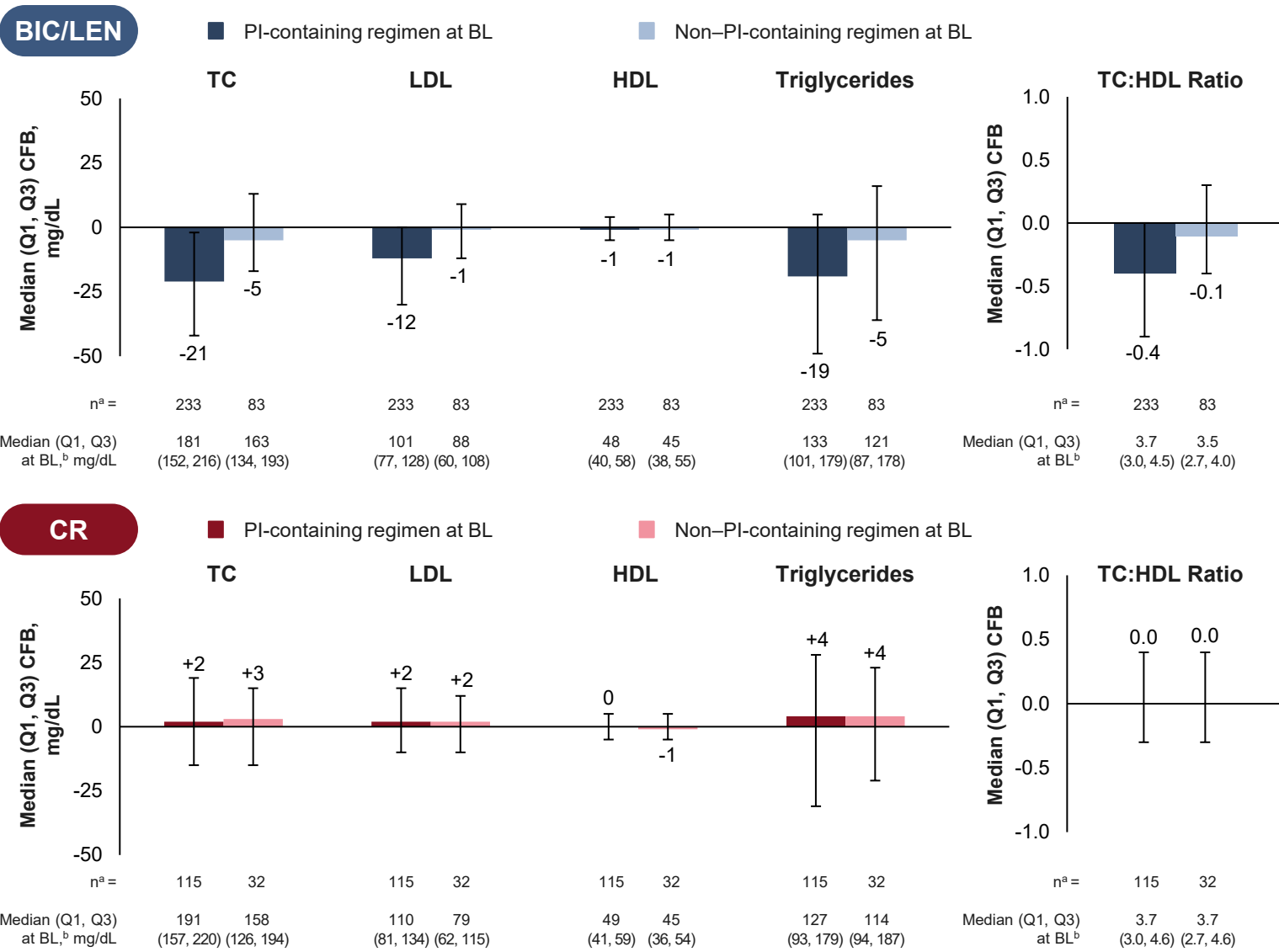
Conclusions

- In this analysis of participants enrolled in Phase 3 of the ARTISTRY-1 study, fasting lipid parameters improved at Week 48 after switching to bictegravir/lenacapavir (BIC/LEN) from complex regimens (CRs), particularly those containing a protease inhibitor (PI)
- Treatment-emergent dyslipidemia was reported in 3% of participants in both treatment groups
- Fasting glucose, hemoglobin A_{1c} (HbA_{1c}), body weight, body mass index (BMI), and systolic/diastolic blood pressure all remained stable in both BIC/LEN and CR groups at Week 48
 - Results were similar in participants taking PI-containing and non-PI-containing regimens at baseline
- These results further support the use of BIC/LEN single-tablet regimen (STR) as a new option for treatment optimization for people with HIV with virologic suppression on a CR, including for those with multiple comorbidities, including dyslipidemia

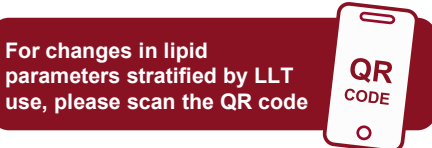
Plain Language Summary

- Some people with human immunodeficiency virus (HIV) need to take several tablets each day (called a complex regimen) because simpler treatments do not work for them or cause side effects
- Bictegravir (BIC) and lenacapavir (LEN) are two HIV medicines that can be taken together as one tablet once a day
- The ARTISTRY-1 study looked at how well BIC/LEN worked in people with HIV who switched from complex regimens
 - BIC/LEN worked equally well at treating HIV and had similar rates of side effects compared with continuing complex regimens over 48 weeks of treatment
- In this analysis from the study, researchers wanted to see whether switching to BIC/LEN affected fat in the blood (cholesterol), how the body breaks down food (metabolism), or body weight, compared with staying on a complex regimen
- After 48 weeks of treatment, researchers found that switching to BIC/LEN lowered levels of cholesterol and other fats in the blood. This effect was greater in participants who were previously taking a type of HIV medicine called a protease inhibitor
 - There were no changes in blood sugar levels, body weight, or blood pressure in people who switched to BIC/LEN or those who stayed on complex regimens

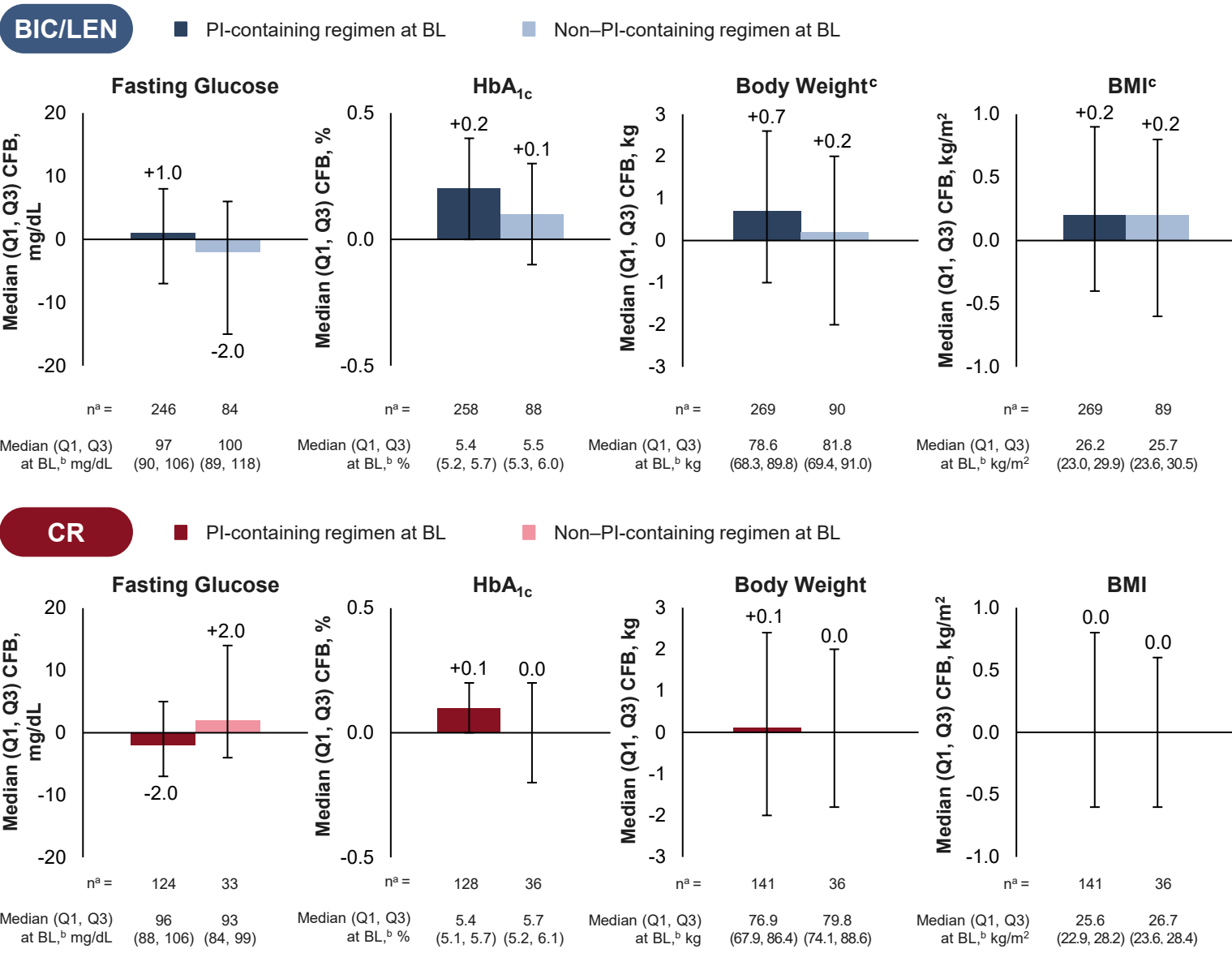
Absolute Change From Baseline in Fasting Lipid Parameters at Week 48



- At Week 48, fasting lipid parameters improved from baseline with BIC/LEN versus CR, particularly in participants switching from PI-containing regimens
- Results were similar between participants taking LLTs at baseline and those not taking LLTs

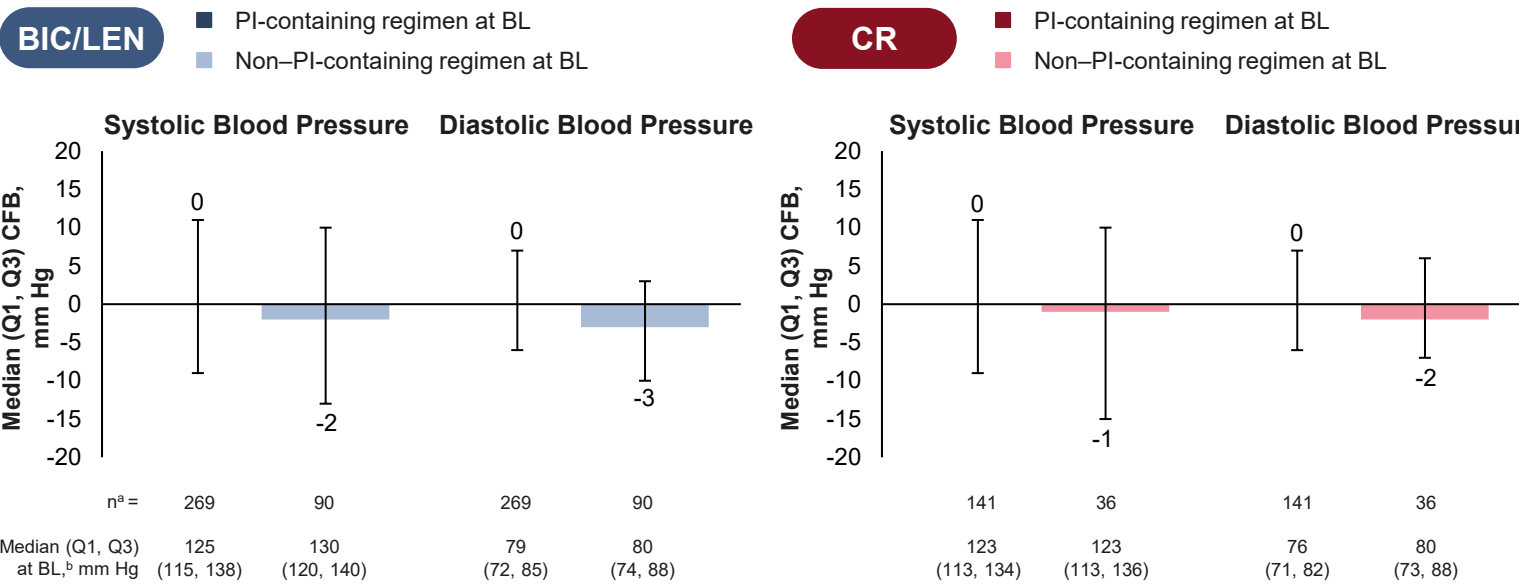


Absolute Change From Baseline in Cardiometabolic Parameters at Week 48



- At Week 48, fasting glucose, HbA_{1c}, body weight, and BMI remained stable in both treatment groups for participants taking PI-containing and non-PI-containing regimens at baseline
- At Week 48, few participants experienced weight gain of > 10% from baseline
 - Among participants in the BIC/LEN group, 3.2% (9/279) of those taking PI-containing regimens and none (0) of those taking non-PI-containing regimens at baseline experienced weight gain of > 10% from baseline
 - Among participants in the CR group, 0.7% (1/148) of those taking PI-containing regimens and none (0) of those taking non-PI-containing regimens at baseline experienced weight gain of > 10% from baseline

Absolute Change From Baseline in Blood Pressure at Week 48



Treatment-Emergent Dyslipidemia Adverse Events

	BIC/LEN		Complex Regimen	
	PI-Containing Regimen at Baseline n = 279	Non-PI-Containing Regimen at Baseline n = 92	PI-Containing Regimen at Baseline n = 148	Non-PI-Containing Regimen at Baseline n = 38
Participants with treatment-emergent dyslipidemia adverse events, n (%) ^a	8 (2.9)	2 (2.2)	4 (2.7)	0
Hypercholesterolemia	1 (0.4)	1 (1.1)	2 (1.4)	0
Dyslipidemia	2 (0.7)	0	1 (0.7)	0
Hyperlipidemia	2 (0.7)	0	1 (0.7)	0
Hypertriglyceridemia	2 (0.7)	1 (1.1)	0	0
Low-density lipoprotein increased	0	0	1 (0.7)	0
Type V hyperlipidemia	1 (0.4)	0	0	0

- All participants who took ≥ 1 dose of the study drug (BIC/LEN or CR) were included in the metabolic outcomes analysis (full analysis set)
- This analysis reports changes from baseline in fasting lipid and glucose parameters, body weight, BMI, and blood pressure at Week 48
- Treatment-emergent dyslipidemia adverse events are also summarized
- Results are presented according to whether participants were receiving a PI-containing or a non-PI-containing ART regimen at baseline
- Changes in fasting lipid parameters are also presented according to use of lipid-lowering treatments (LLTs) at baseline

Results

Baseline Demographics and Clinical Characteristics

	BIC/LEN ^a		Complex Regimen	
	PI-Containing Regimen at Baseline n = 279	Non-PI-Containing Regimen at Baseline n = 92	PI-Containing Regimen at Baseline n = 148	Non-PI-Containing Regimen at Baseline n = 38
Age, years, median (range)	60 (22-81)	62 (36-84)	60 (24-75)	61 (49-75)
Female sex at birth, n (%)	43 (15.4)	21 (22.8)	30 (20.3)	6 (15.8)
Race, n (%) ^b				
White	197 (70.6)	63 (68.5)	99 (66.9)	31 (81.6)
Black	53 (19.0)	11 (12.0)	29 (19.6)	4 (10.5)
Asian	13 (4.7)	3 (3.3)	8 (5.4)	1 (2.6)
Other ^c	6 (2.2)	6 (6.5)	3 (2.0)	0
Hispanic or Latino, n (%) ^d	69 (24.7)	11 (12.0)	35 (23.6)	7 (18.4)
Select comorbidities, n (%) ^{d,f}				
Dyslipidemia	192 (68.8)	52 (56.5)	102 (68.9)	31 (81.6)
Hypertension	134 (48.0)	56 (60.9)	66 (44.6)	24 (63.2)
Hyperglycemia/diabetes mellitus	61 (21.9)	30 (32.6)	26 (17.6)	16 (42.1)
Chronic kidney disease	37 (13.3)	12 (13.0)	21 (14.2)	8 (21.1)
HbA _{1c} at baseline, %, median (Q1, Q3) in participants with hyperglycemia/diabetes mellitus	5.4 (5.2, 5.7) [n = 271] 6.0 (5.4, 6.8) [n = 59]	5.5 (5.3, 6.0) [n = 90] 6.4 (5.8, 7.2) [n = 29]	5.4 (5.1, 5.7) [n = 139] 6.2 (5.7, 6.7) [n = 26]	5.7 (5.2, 6.1) [n = 38] 6.4 (5.8, 7.2) [n = 16]
Select concomitant non-antiretroviral medications, n (%) ^g				
1	49 (17.6)	13 (14.1)	43 (29.1)	7 (18.4)
≥ 2	180 (64.5)	57 (62.0)	76 (51.4)	26 (68.4)
Antidiabetics	62 (22.2)	22 (23.9)	31 (20.9)	13 (34.2)
Antihypertensives	147 (52.7)	56 (60.9)	74 (50.0)	27 (71.1)
Lipid-lowering agents	205 (73.5)	57 (62.0)	106 (71.6)	28 (73.7)

^aTwo (< 1%) participants in the BIC/LEN group were on an efavirenz-containing regimen at baseline. ^bLocal regulators did not allow the collection of race information for 36 participants (BIC/LEN PI-containing regimen at baseline, n = 10; BIC/LEN non-PI-containing regimen at baseline, n = 6; CR PI-containing regimen at baseline, n = 9; CR non-PI-containing regimen at baseline, n = 8); percentages were calculated using total number of participants as the denominator. ^cCategory includes American Indian or Alaska Native, Native Hawaiian or Pacific Islander, and Other. ^dLocal regulators did not allow the collection of ethnicity information for 37 participants (BIC/LEN PI-containing regimen at baseline, n = 12; BIC/LEN non-PI-containing regimen at baseline, n = 9; CR PI-containing regimen at baseline, n = 8; CR non-PI-containing regimen at baseline, n = 8); percentages were calculated using total number of participants as the denominator. ^eCategories are not mutually exclusive. ^fGrouped terms on standardized MedDRA query narrow search. ^gConcomitant medications were those taken while on study drug or complex regimen. Medications collected were coded using WHO Drug Dictionary BMAR25. Select concomitant medications include antidiabetic agents (including drugs with WHO ATC2^g "drugs used in diabetes"), antihypertensive agents (including drugs with WHO ATC2^g "agents acting on the renin-angiotensin system", "antihypertensives" [excluding ATC3^g "other antihypertensives"], "beta-blocking agents", "calcium channel blockers", or "diuretics"), and lipid-lowering agents (including drugs with WHO ATC2^g "lipid-modifying agents"). ATC, Anatomical Therapeutic Chemical [level]; BIC, bictegravir; HbA_{1c}, hemoglobin A_{1c}; LEN, lenacapavir; MedDRA, Medical Dictionary for Regulatory Activities; PI, protease inhibitor; Q, quartile; WHO, World Health Organization.

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Acknowledgments: We thank all study participants, investigators, and staff. This study was sponsored by Gilead Sciences, Inc. Medical writing support was provided by Jack Seymour, BS^c (Aspire Scientific Ltd, UK), and was funded by Gilead Sciences, Inc.

Disclosures: ILC reports payments or honoraria for lectures from Gador Argentina, Gilead Sciences, Inc., Merck, and Sequirus; and support for attending meetings and/or travel from Gador Argentina and Richmond Argentina. PJR reports speaker payments or honoraria from Gilead Sciences, Inc. and Viiv Healthcare. TL reports grants or contracts from AbbVie, Charité Berlin, Deutsche Lebensmittelforschung, Gilead Sciences, Inc., GSK/Viiv Healthcare, ImmunoTherapeutics Heidelberg, Janssen-Cilag, Moderna, and MSD. JIB reports consulting fees from MSD and Viiv Healthcare; payments or honoraria from Gilead Sciences, Inc. and Viiv Healthcare; and support for attending meetings and/or travel from Gilead Sciences, Inc. VP reports honoraria from Gilead Sciences, Inc., MSD, and Viiv Healthcare; and support for attending meetings and/or travel from Gilead Sciences, Inc. XZ, PS, and JMM-R are employees of, and hold stock in, Gilead Sciences, Inc. KM reports consulting fees for advisory boards from Gilead Sciences, Inc., Merck, Thera, and Viiv Healthcare; payments or honoraria from Epivian, Gilead Sciences, Inc., Janssen Therapeutics, Merck, and Viiv Healthcare; and participation on a data safety monitoring board or advisory board for Epivian, Gilead Sciences, Inc., Janssen Therapeutics, Merck, and Viiv Healthcare.

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