



ONCOLOGY

ESMO Update
September 21, 2020

Lilly



Agenda

Introduction

Anne White, President, Lilly Oncology

Verzenio Update

Dr. Maura Dickler, Vice President, Late Phase Oncology Development

Closing Remarks

Dr. Dan Skovronsky, Chief Scientific Officer

Q&A

SAFE HARBOR PROVISION



This presentation contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. The company's results may be affected by factors including, but not limited to, the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; the extent and duration of the effects of the COVID-19 pandemic; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform.

For additional information about the factors that affect the company's business, please see the company's latest Forms 10-K, 10-Q, and any 8-Ks filed with the Securities and Exchange Commission.

The company undertakes no duty to update forward-looking statements

The background of the slide is a solid red color. Overlaid on this background is a complex network diagram. It consists of numerous circular nodes of varying sizes, connected by thin, light-colored lines. The nodes are distributed across the entire frame, with some appearing as small dots and others as larger, more prominent circles. The connections between the nodes form a web-like structure, with some nodes having multiple links and others being isolated or part of small clusters. The overall effect is a sense of interconnectedness and complexity.

Introduction

LILLY ONCOLOGY UPDATES SINCE ESMO 2019



PIPELINE UPDATES

Verzenio®

- ✓ monarchE positive Phase 3 data at preplanned interim analysis

Tyvyt®

- ✓ Phase 3 data in 1L NSCLC in combination with Alimta and platinum

LOXO-305

- ✓ Promising Phase 1 data at ASH 2019
- ✓ Additional data expected in 2020

SERD

- ✓ Initiated Phase 1 program late in 2019

NEW WAYS TO INNOVATE



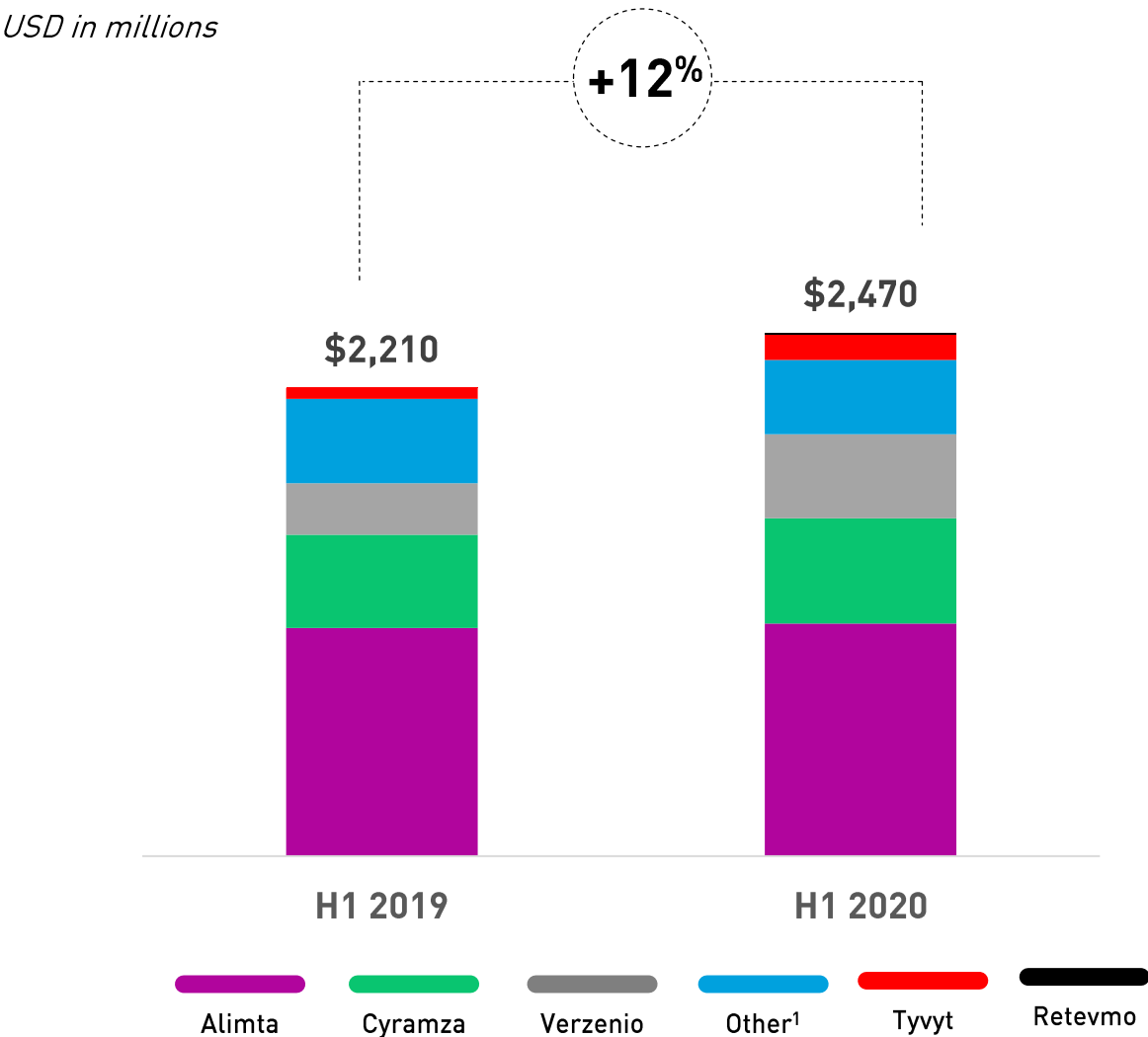
COMMERCIAL EXECUTION

- ✓ Launching Retevmo™ and driving uptake of key growth products
- ✓ Sustained performance from foundational brands
- ✓ Leveraging and enhancing virtual capabilities

LILLY ONCOLOGY 1H 2020 PERFORMANCE



REVENUE GROWTH



KEY GROWTH DRIVERS



Strong launch and uptake highlighting virtual capabilities



Tyvyt² continues strong performance, with additional indications under development



Solid growth year-to-date despite impact of COVID-19



Sales growth of 63% versus 1H 2019

¹Other includes: Elunate, Lartruvo, Erbitux, Gemzar and Vitrakvi

²In collaboration with Innovent Biologics, Inc.

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Verzenio Update

VERZENIO MONARCH CLINICAL PROGRAM



Monotherapy after chemotherapy



China registrational data

Focus Today

EARLY BREAST CANCER
Combination with endocrine therapy (ET) vs. ET alone in early breast cancer



Combination with fulvestrant after endocrine therapy



Combination with NSAI as initial therapy for metastatic disease



Phase 2 data in 3L HER2+

monarchE FURTHER DIFFERENTIATES VERZENIO



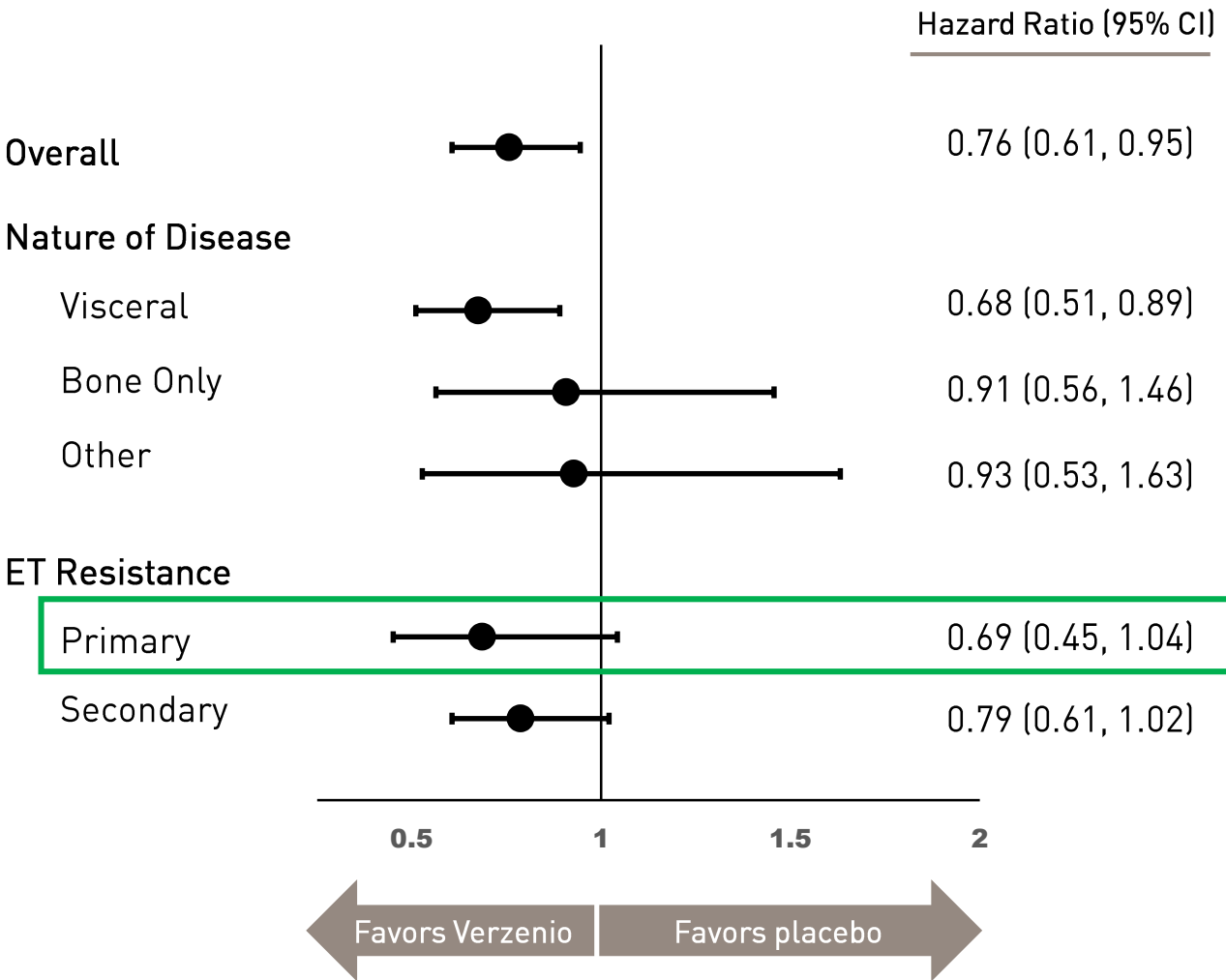
Continuous Dosing	✓	✗	✗
FDA Approval as Monotherapy	✓ monarch 1	✗	✗
Statistically Significant Overall Survival Benefit in Metastatic Breast Cancer	✓ monarch 2 <i>Additional AI trial ongoing in 1L post-menopausal setting</i>	✗ PALOMA-3 <i>Additional AI trial ongoing in 1L post-menopausal setting</i>	✓ MONALEESA-3 & 7 <i>Additional AI trial ongoing in 1L post-menopausal setting</i>
Positive Trial in Adjuvant Setting	✓ monarch E EARLY BREAST CANCER	✗ PALLAS <i>(PENELOPE-B adjuvant trial ongoing, late 2020 readout)</i>	? NATALEE <i>(2022 Interim, 2025 Primary readout)</i>

MONARCH 2 OVERALL SURVIVAL (OS) DATA



OS BY STRATIFICATION FACTORS

STRONG DATA IN SUBGROUPS



- **Striking result in a primary endocrine resistant* population**
 - Reinforced our conviction monarchE would show benefit
 - OS result in subgroup not seen in all CDK4 & 6 agents
- **Pronounced OS results in visceral disease, demonstrating benefit in patients with a poorer prognosis**

*Primary Endocrine Resistance (ESMO guidelines): relapse while on the first 2 years of adjuvant ET, or PD within first 6 months of 1st line ET for MBC, while on ET

Abstract LBA6. Presented at the European Society for Medical Oncology; September 27-October 1, Barcelona, Spain

monarchE STUDY OVERVIEW



PATIENT POPULATION

- **HR+, HER2- high risk early breast cancer**
- **High risk defined as:**
 - 4 or more positive axillary lymph nodes OR
 - 1-3 positive axillary lymph nodes and 1 of below:
 - Tumor size 5 centimeters or more
 - Histologic grade 3
 - Centrally tested Ki-67 20% or more
- **Pre/postmenopausal**
- **With or without prior adjuvant/neoadjuvant chemotherapy**

STUDY DESIGN

- **Two arms, randomized 1:1**
 - Verzenio (150mg BID up to 2 years) + Standard of Care (SOC) Endocrine Therapy (5-10 years)
 - SOC Endocrine Therapy (5-10 years)
- **Primary Endpoint: Invasive disease-free survival (STEEP criteria)**
- **Key Secondary Endpoints:**
 - Distant relapse-free survival
 - Overall survival
 - Safety
- **Prespecified stratification factors**
 - Prior chemotherapy
 - Menopausal status
 - Region

monarchE STUDIED A HIGH-RISK POPULATION



HIGH RISK DISEASE CHARACTERISTICS

DIVERSITY AMONG CHARACTERISTICS

All numbers %		Verzenio + ET (n = 2,808)	ET alone (n = 2,829)
Number of positive lymph nodes	0	0.2	0.2
	1-3	39.9	40.4
	4 or more	59.8	59.3
Histological grade	Grade 1	7.4	7.6
	Grade 2	48.9	49.3
	Grade 3	38.8	37.7
Primary tumor size by pathology following definitive surgery	<20 mm,	27.8	27.0
	≥20 mm to <50mm	48.8	50.2
	≥50 mm	21.7	21.6
Central Ki-67	<20%	33.9	34.4
	≥20%	44.9	43.6
	Unavailable	21.1	22.0
Progesterone receptor status	Positive	86.2	86.7
	Negative	10.6	10.4

- Full range of multiple disease characteristics representative of patients with high risk of recurrence
- Representation of both patients with 4+ positive lymph nodes (~60%) and 1-3 nodes with additional risk factors (~40%)
- Population balanced between study arms

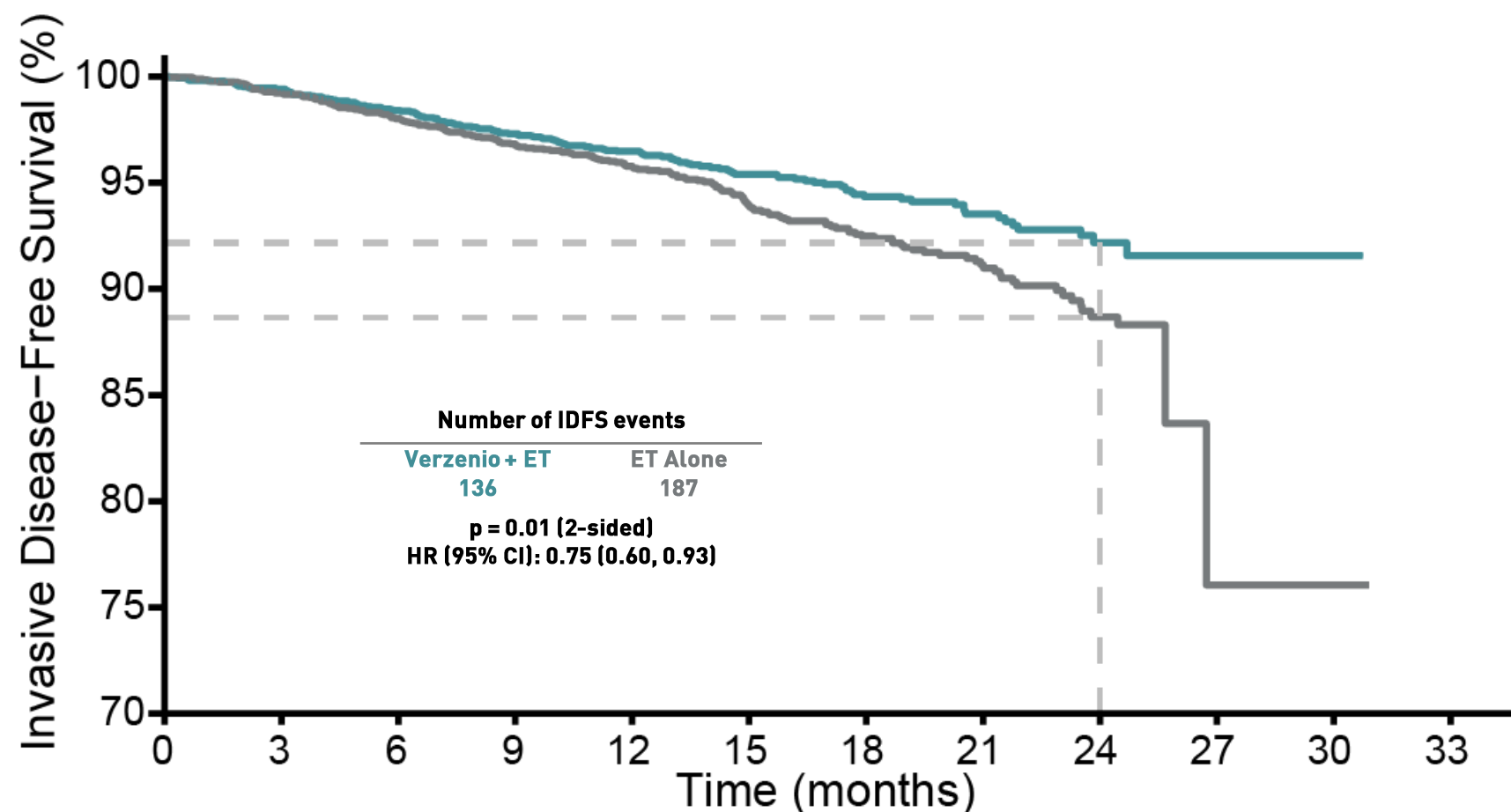
Note: where values do not add up to 100%, remaining data are missing, unavailable or could not be assessed
LBA5. Presented at the European Society for Medical Oncology Virtual Meeting; September 19-21

monarchE INVASIVE DISEASE-FREE SURVIVAL (IDFS)



VERZENIO SIGNIFICANTLY REDUCED RISK OF CANCER RECURRENCE BY 25%

- Only CDK4 & 6 inhibitor to demonstrate benefit in this setting
- Achieved definitive results at a pre-planned interim analysis (323 events)
- Statistically significant and clinically meaningful benefit



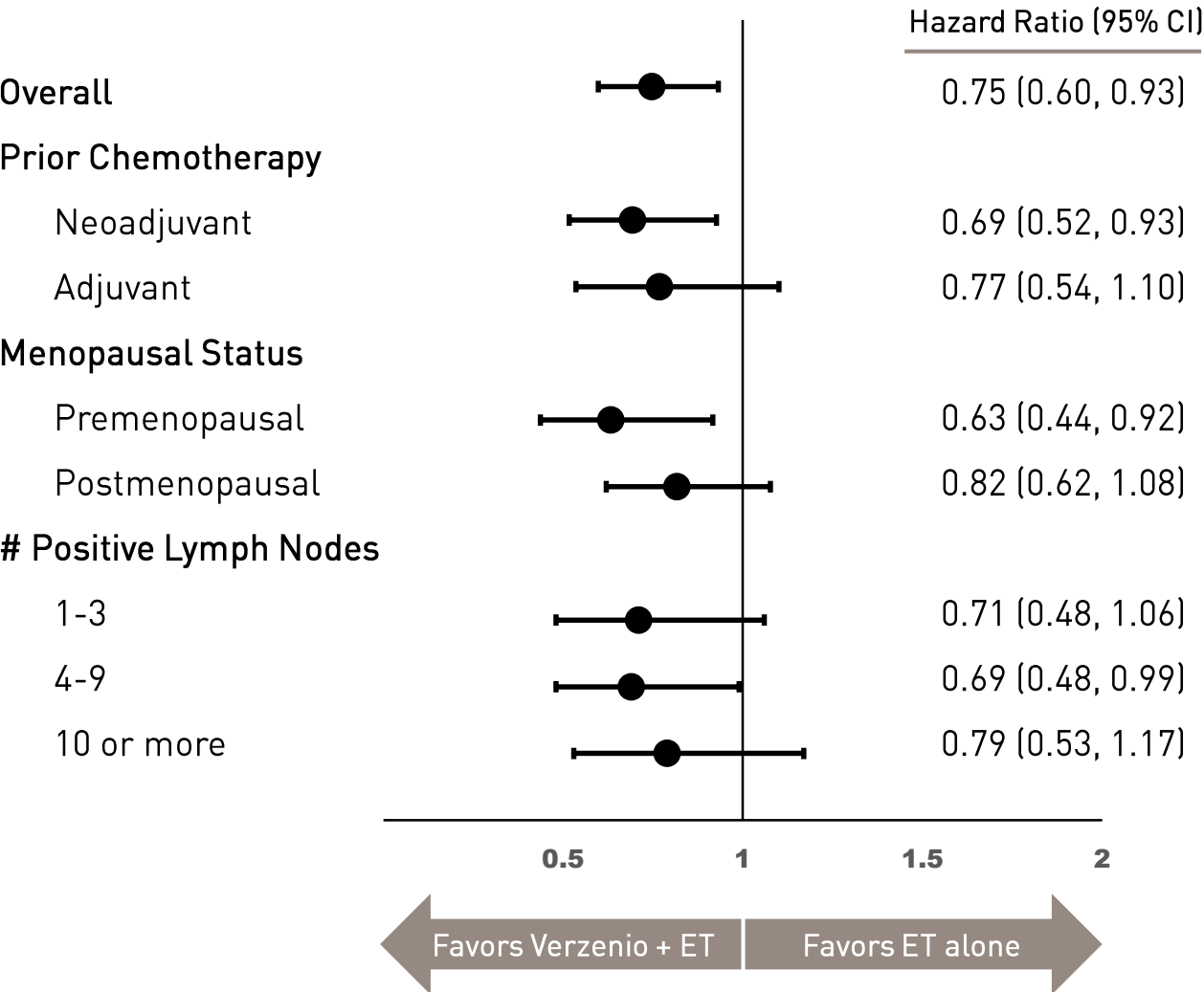
**Two-year IDFS rates were 92.2% (Verzenio + ET arm) and 88.7% (ET arm) – 3.5% absolute difference.
Consistent results across all prespecified subgroups**

monarchE BENEFIT CONSISTENT ACROSS SUBGROUPS



IDFS IN SELECT SUBGROUPS

CONSISTENT RESULTS



- Consistent results observed across all prespecified stratification factors: prior chemotherapy, menopausal status, and region (not shown)
- Patients with prior neoadjuvant chemotherapy showed 31% reduction in risk of recurrence
- Consistent IDFS results across patients enrolled with 4+ nodes and 1-3 nodes with other risk factors

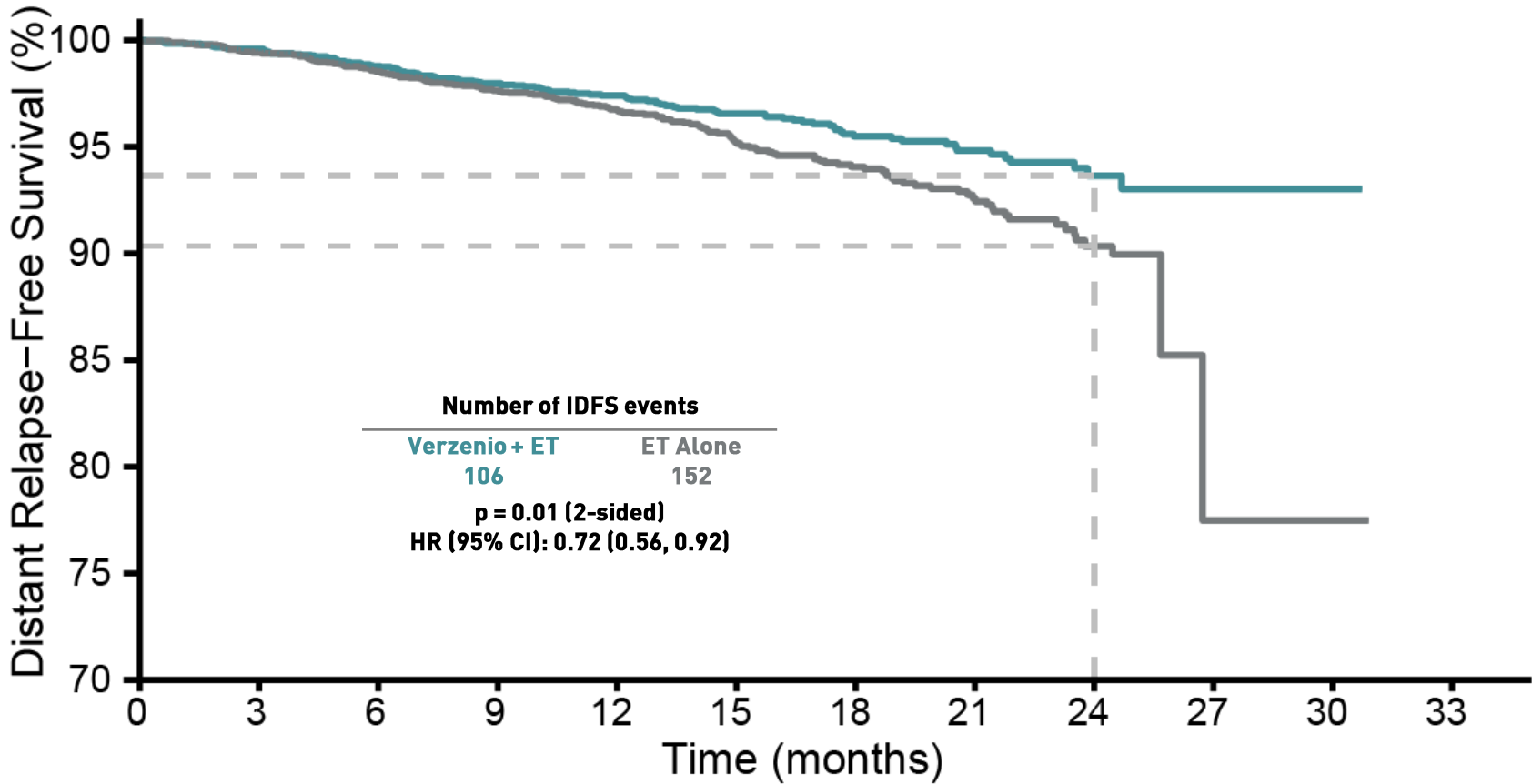
LBA5. Presented at the European Society for Medical Oncology Virtual Meeting; September 19-21

monarchE DISTANT RELAPSE-FREE SURVIVAL (DRFS)



VERZENIO REDUCED THE RISK OF DISTANT METASTASES BY 28%

- DRFS benefit leading indicator for potential to demonstrate overall survival benefit⁽¹⁾
- Consistent with IDFS, clinically meaningful result in DRFS, a key secondary endpoint
- Overall survival data immature



Two-year DRFS rates were 93.6% (Verzenio + ET arm) and 90.3% (ET arm) – 3.3% absolute difference.
DRFS results consistent across all prespecified subgroups

⁽¹⁾Per STEEP criteria paper (Hudis et al.): “Of all the nondeath events listed above, it is generally accepted that distant recurrence (metastasis) trumps other events because it is a threat to patient survival. Indeed, it is the main predictor of death in all end point definitions.”

LBA5. Presented at the European Society for Medical Oncology Virtual Meeting; September 19-21



TEAE of 20% or greater in either arm
All numbers are %

	Verzenio + ET n = 2,791			ET Alone n = 2,800		
	Any grade	Grade 3	Grade 4	Any grade	Grade 3	Grade 4
Diarrhea	82.2	7.6	0	7.1	0.1	0
Neutropenia	44.6	18.0	0.6	5.0	0.6	0.1
Fatigue	38.4	2.8	0	15.5	0.1	0
Leukopenia	36.8	10.8	0.1	6.1	0.4	0
Abdominal pain	34.0	1.3	0	8.1	0.3	0
Nausea	27.9	0.5	0	8.0	0.0	0
Anemia	22.9	1.7	0.0	3.2	0.3	0
Arthralgia	20.5	0.2	0	31.3	0.6	0
Hot flush	14.1	0.1	0	21.0	0.3	0
Additional AEs of interest						
Aspartate aminotransferase increase	9.2	1.5	0.1	3.8	0.5	0
Alanine aminotransferase increase	9.5	2.1	0.2	4.3	0.6	0
Alopecia	9.1	0	0	1.9	0	0
Venous thromboembolic event	2.3	1.0	0.2	0.5	0.1	0
Interstitial lung disease	2.7	0.3	0	1.2	0	0

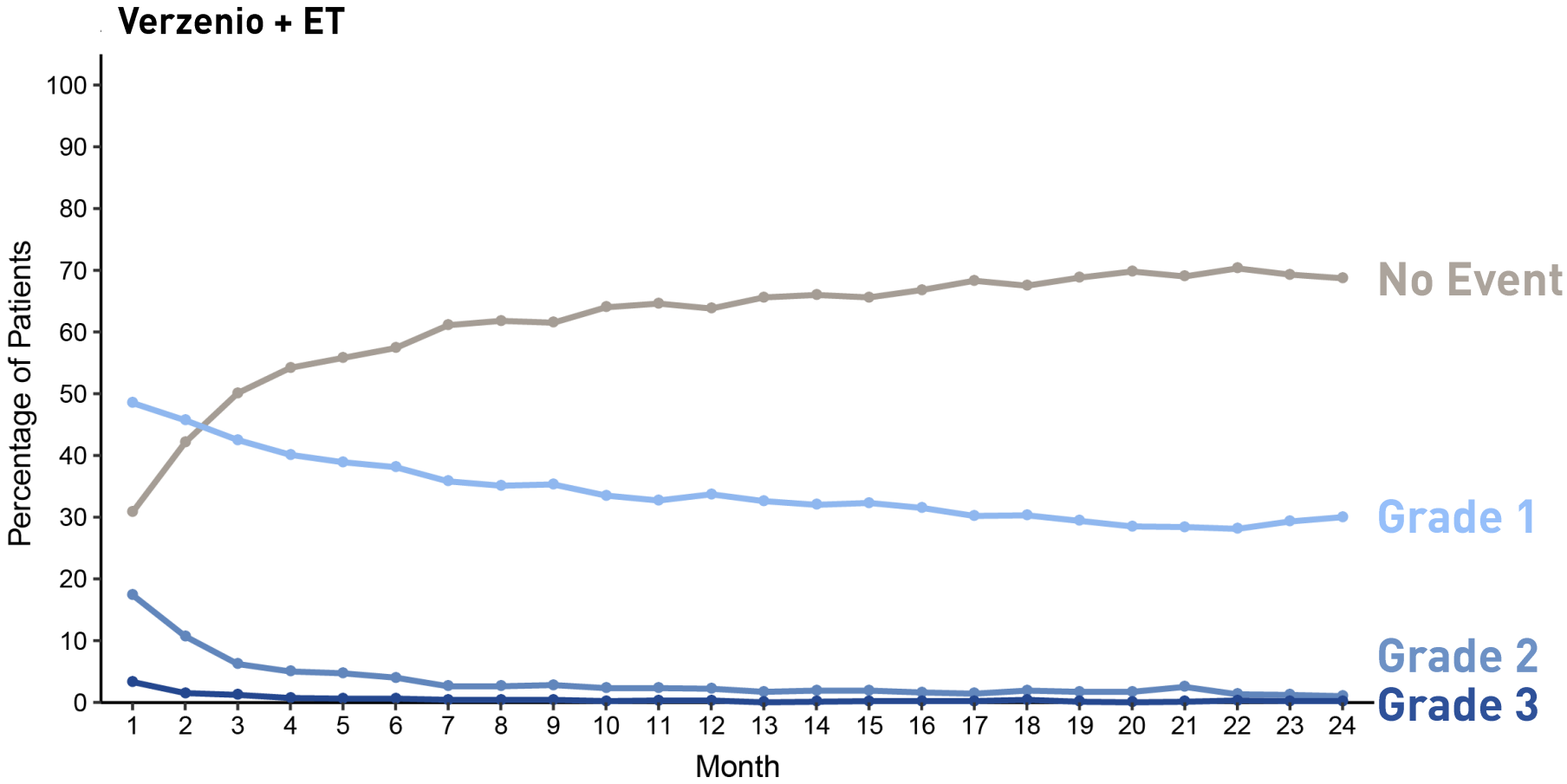
No new safety signals observed

Adverse event management strategies consistent with label



PREDICTABLE AND MANAGEABLE

- Frequency and severity decreased meaningfully over time
- Discontinuation rate due to this side effect was less than 5%
- Median onset and duration
 - Time to onset: 8 days
 - Grade 2 duration: 6 days
 - Grade 3 duration: 5 days



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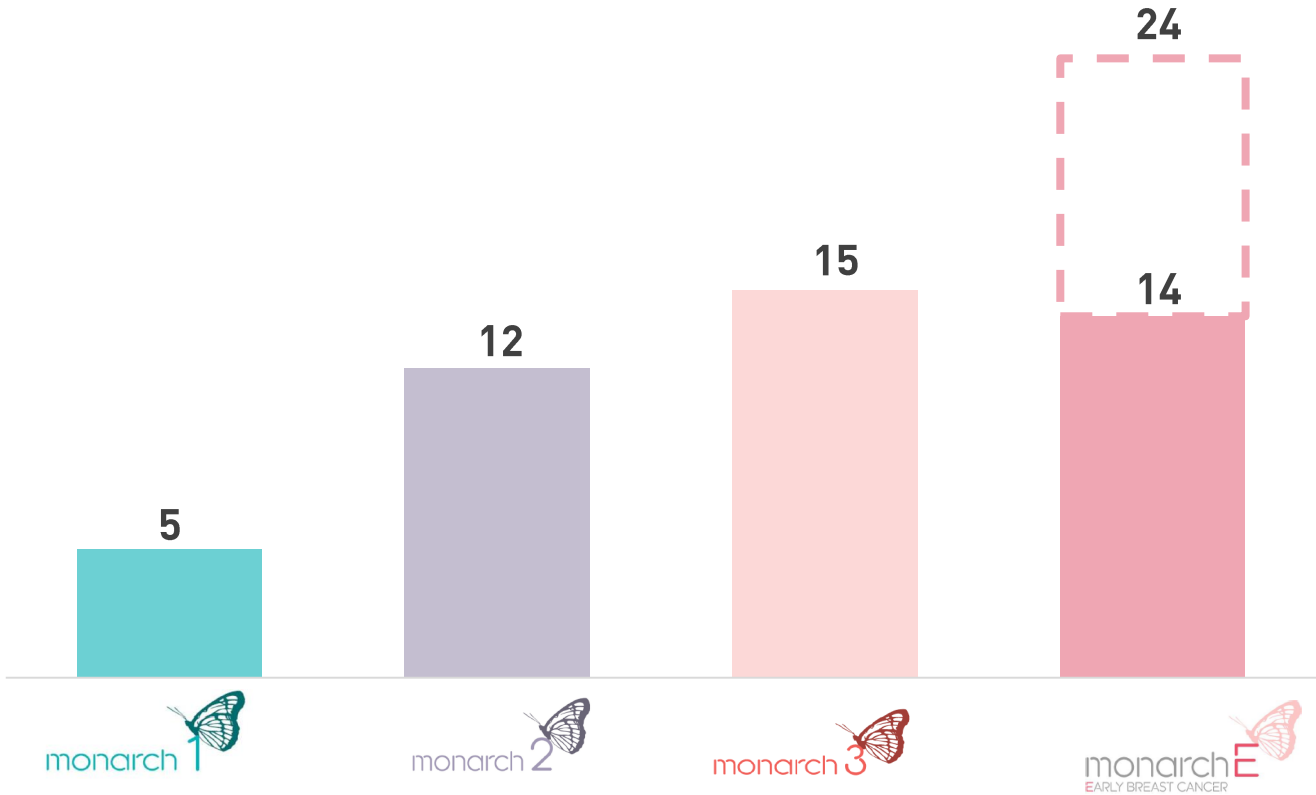
CTCAE grading
G1: <4 stools over baseline/day
G2: 4-6 stools over baseline/day
G3: >6 stools over baseline/day

DURATION OF THERAPY EXPECTED TO INCREASE



VERZENIO DURATION OF THERAPY

Months



Source: Verzenio USPI

monarchE duration of therapy per protocol
 monarchE duration of therapy as observed at data cutoff

monarchE DURATION

- Median follow-up at interim analysis was 15.5 months in each arm
- Over 70% of patients were still in 2-year treatment period
- Median duration on Verzenio at data cutoff was 14 months
- Study is ongoing and median duration on therapy will continue to increase

Verzenio Summary



Only CDK4 & 6 inhibitor to demonstrate benefit in early breast cancer

Have been very few treatment advances in adjuvant therapy for HR+, HER2- early breast cancer in nearly 20 years



Further demonstrates unique attributes of Verzenio and differentiation versus other agents

Adds to existing compelling body of evidence that already includes overall survival data in metastatic breast cancer



Significantly increases Verzenio's addressable market

Based on monarchE entry criteria, estimate more than 20,000 additional patients in the U.S. alone, increasing addressable market over 50%

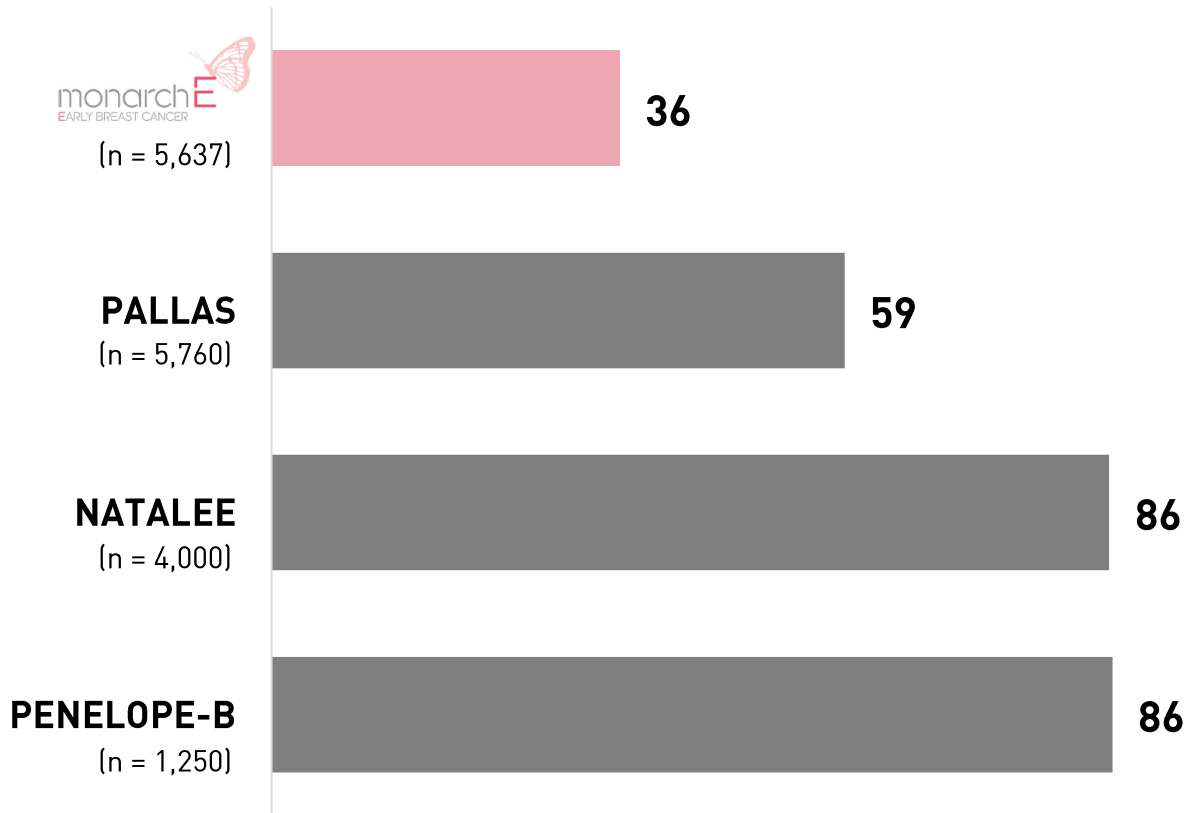
The background of the slide features a complex, abstract network pattern. It consists of numerous small, semi-transparent red circles of varying sizes, interconnected by thin, light red lines. These lines and dots form a web-like structure that spans the entire frame, creating a sense of connectivity and complexity. The overall aesthetic is modern and technological.

Closing Remarks

ACCELERATING SPEED OF DEVELOPMENT



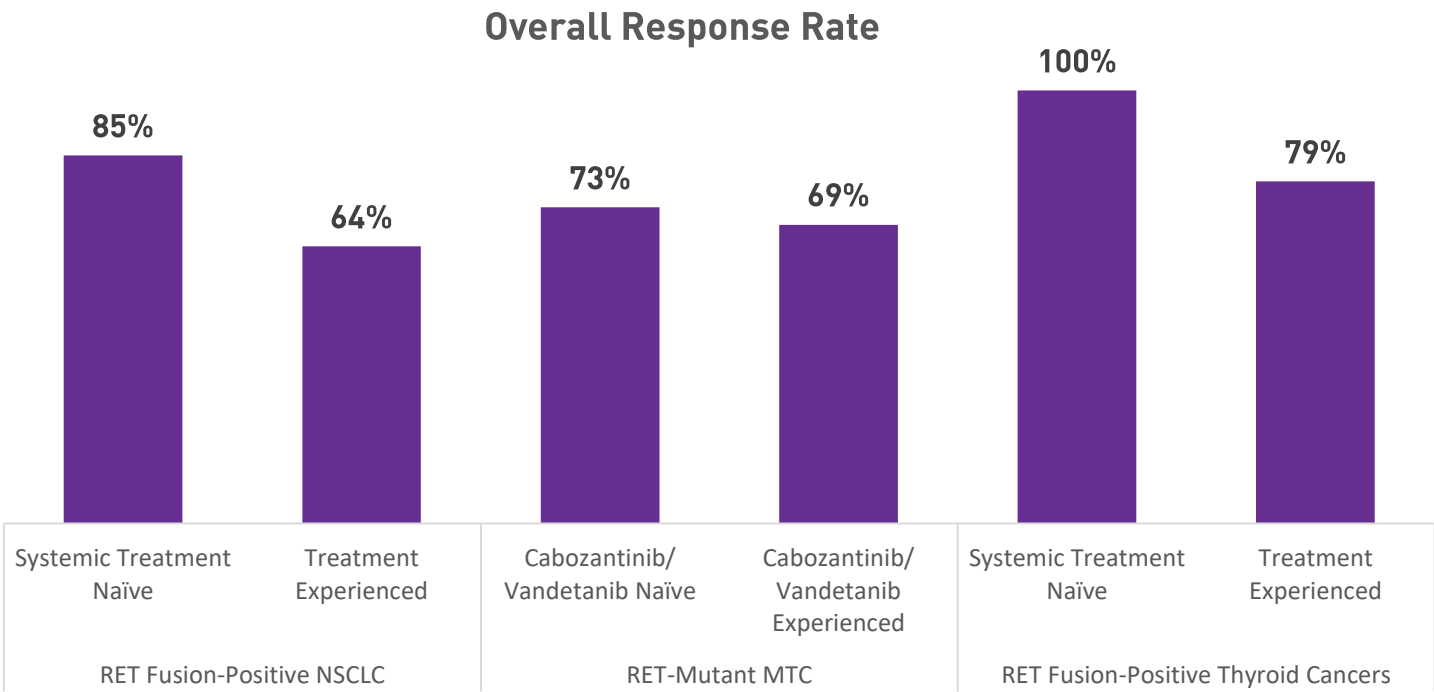
Months From Study Start to Topline Data⁽¹⁾



The most rapid timeline in the development of an oncology medicine with multiple indications

Less than 3 Years

First Human Dose to Approval



⁽¹⁾ Topline data defined as topline press release or primary completion date per clinicaltrials.gov
Note: Trials enrolled different populations and had different treatment durations

Source: US Retevmo label

NEXT STEPS



VERZENIO

- monarchE data to be submitted by end of the year
- monarchE will continue to final analysis of overall survival
- Initiate Phase 3 trial in HR+, HER2+ early breast cancer
- Regulatory action for Verzenio in HR+, HER2-metastatic breast cancer in China

LILLY ONCOLOGY

- **Research model that combines best of biotech and large-cap pharma**
 - Unique leadership model with Loxo Oncology at Lilly
 - Focus of biotech, scale and expertise of pharma
- **Augment internal research with business development**
 - Pursue high conviction science external opportunities
- **Data from promising early-stage programs**
 - LOXO-305
- **Rapidly advance preclinical portfolio to drive next wave of new medicines**

Summary



Significant momentum in Lilly's oncology business

Meaningful progress in commercial execution and advancing our pipeline



Pipeline acceleration in oncology exemplifies efforts to speed development of new medicines

Operational execution combined with external innovation



Future is bright for Lilly

Early phase portfolio progressing, and next wave of new medicines rapidly approaching the clinic



QUESTIONS AND ANSWERS

**LILLY UNITES
CARING WITH DISCOVERY
TO CREATE MEDICINES THAT
MAKE LIFE BETTER
FOR PEOPLE
AROUND THE WORLD**

Lilly