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I have served as a consultant* for

- **Astra Zeneca**
- **Boehringer-Ingelheim**
- **Pfizer**
- **Takeda**

* Unrelated to the current presentation

PROJECT PRIORITY

PATIENT **R**EPORTED **I**NITIATIVE **O**N **R**ESISTANCE, **I**NCIDENCE, **T**REATMENT STUD**Y**

October 12, 2019

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WHAT IS PROJECT PRIORITY?

- **Patient-founded** and **patient-driven** research partnership between the EGFR Resisters and LUNGevity Foundation
- Study Objectives:
  - Understand needs of EGFR-positive lung cancer community
  - Identify areas for improvement in diagnosis and treatment
  - Give voice to patient concerns regarding risk factors, treatments, and symptom and side-effect management

COLLECTING REAL-WORLD PATIENT-REPORTED DATA USING A PATIENT EXPERIENCE SURVEY

- Quantitative survey developed with input from patients, caregivers, clinicians, and regulators

- International survey (only in English) open to patients with a diagnosis of EGFR-positive lung cancer and their caregivers

- 130-question <u>longitudinal</u> survey covering specific domains:

Demographics/Risk Factors

Diagnostic and treatment journey (including complementary care & adverse event management)

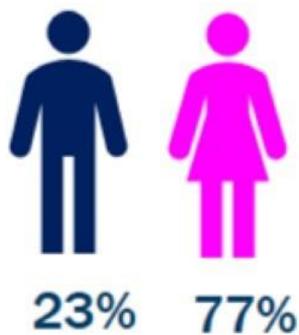Quality of life/Psychosocial impact of diagnosis

Patient experience

Identify areas for improvement in diagnosis and treatment

PARTICIPANT DEMOGRAPHICS

350 participants included in analysis (survey response rate = 30%). Longitudinal component ongoing

27% international participants (ex-US)

Ex-US: Europe (48%), Australia (23%), Asia (20%), South America (9%)

23% **77%**

Active versus environmental tobacco exposure

18.1% **42.3%**

Variable	US	Ex-US
Diagnosed in the past 5 years	83.6%	88.2%
Average age (± S.D.)	56 (10.3)	53 (12.3)

Likelihood of developing T790M mutation after first-line treatment (using forward regression)

Afatinib, 2.5X **Erlotinib, 3.3X**

TREATMENT JOURNEY OF US AND EX-US PARTICIPANTS

	Variable	US	Ex-US
No of lines of therapy received	One	45.6%	60.6%*
	Two	26.6%	25.2%
	Three or more	27.8%	14.2%*
First-line therapy	Combination***	27.0%	13.8%*
	Erlotinib	29.0%	35.7%
	Afatinib	12.0%	18.4%
	Gefitinib	0.0%	13.3%*
	Osimertinib	37.4%	15.3%*
	Chemotherapy	17.3%	10.2%*
	Immunotherapy	4.2%	0.0%

		US	Ex-US
Brain metastasis present	Yes	53.1%	41%*
Type of treatment for brain metastasis	Whole brain radiation	13.8%	26%*
	SRS	59.8%	55.0%
	Surgery	15.0%	15.1%
	Controlled by TKI**	42.5%	35.0%*

*- significantly different from US respondents at p < 0.05 by Chi-square
** - Did not receive surgery or radiation
N = 350

*- significantly different from US respondents at p < 0.05 by Chi-square
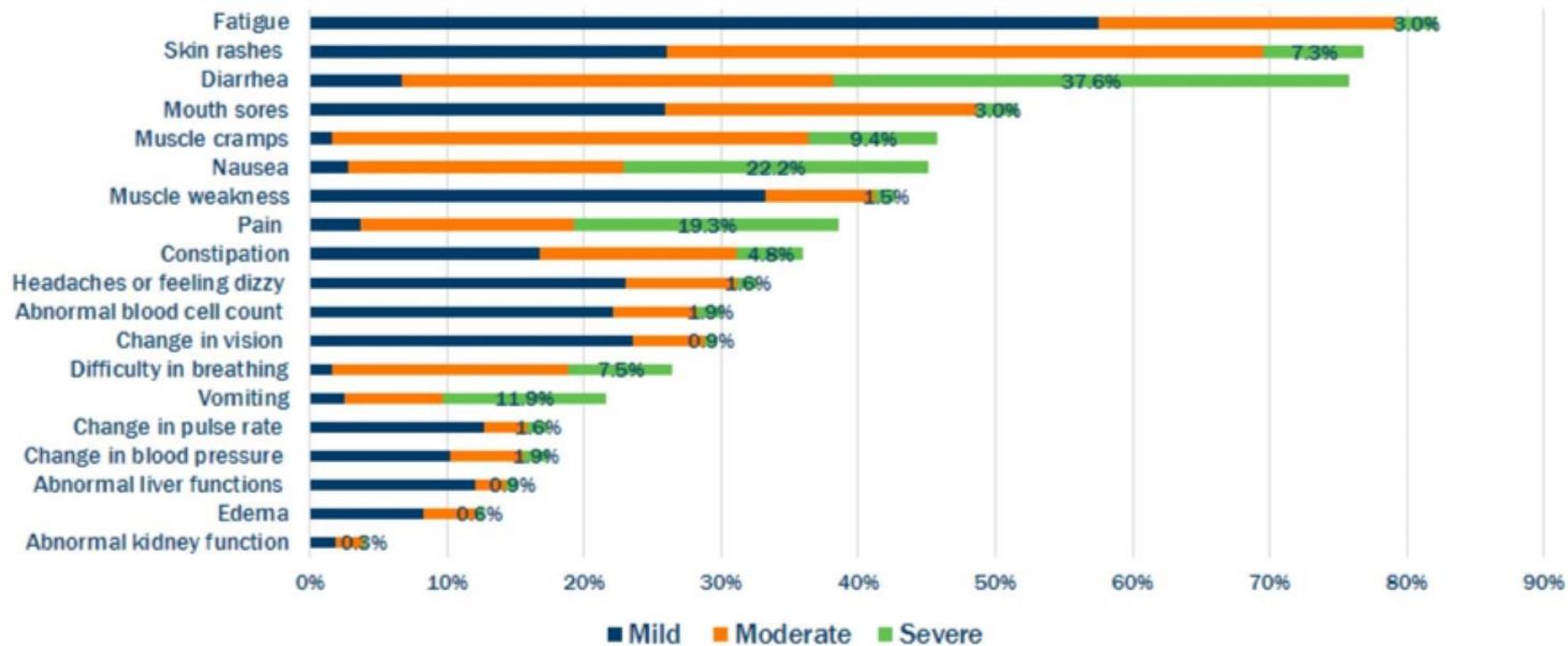*** - Combination = TKI + chemo or TKI + angiogenesis inhibitor//Excludes radiation
N = 350

FIRST-LINE EGFR TKI USE OVER TIME

United States

Ex - United States

Legend: Erlotinib, Afatinib, Gefitinib, Osimertinib, Dacomotinib

N = 255

N = 95

Variation in prescribing preferences between US and ex-US due to: approval and availability

Data for each year is the absolute number of respondents who reported using a specific therapy

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SIDE EFFECT PROFILE OF FIRST-LINE TREATMENT

Legend: ■ Mild ■ Moderate ■ Severe

Categories (top to bottom): Fatigue (3.0%), Skin rashes (7.3%), Diarrhea (37.6%), Mouth sores (3.0%), Muscle cramps (9.4%), Nausea (22.2%), Muscle weakness (1.5%), Pain (19.3%), Constipation (4.8%), Headaches or feeling dizzy (1.6%), Abnormal blood cell count (1.9%), Change in vision (0.9%), Difficulty in breathing (7.5%), Vomiting (11.9%), Change in pulse rate (1.6%), Change in blood pressure (1.9%), Abnormal liver functions (0.9%), Edema (0.6%), Abnormal kidney function (0.3%)

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RATE OF HOSPITALIZATION AMONG RESPONDENTS

Have you ever been hospitalized because of your lung cancer?

US
- 39.5%
- 60.6%
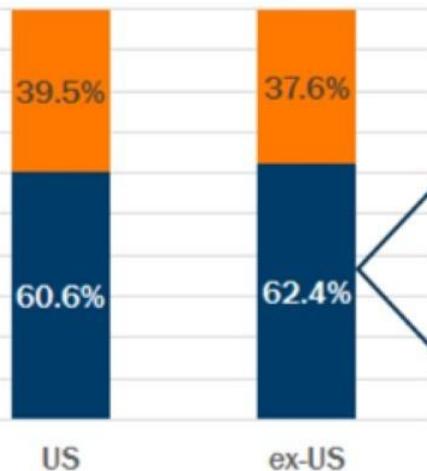
ex-US
- 37.6%
- 62.4%

■ Yes ■ No

61% of respondents report hospitalization during their tx journey

N = 350

Hospitalization statistics	US	Ex-US
Number of times hospitalized ($\pm$ S.D.)	1.9 ± 1.7	2 ± 1.5
Total number of days hospitalized ($\pm$ S.D.)	8 ± 8.2	10.9 ± 9.1

N = 214

| Reason for hospitalization	US	Ex-US
Lung disease (asthma, COPD) worsened	1.2%	1.6%
Developed heart disease/Heart disease worsened	0.6%	0.0%
Due to symptoms related to the lung cancer	40.5%	34.4%
Due to side effects of treatment	18.5%	21.9%

N = 214

Major causes
- Pulmonary embolism, Seizures
- Diarrhea (1st and 2nd generation TKI alone or in combination are major predictors)

Presence of co-morbidities
- 80% report no co-morbidities (common co-morbidities include asthma and diabetes)
- Respiratory co-morbidities: No IPF or ILD reported by respondents; 2% reported COPD

RATE OF DIAGNOSED DEPRESSION AMONG RESPONDENTS

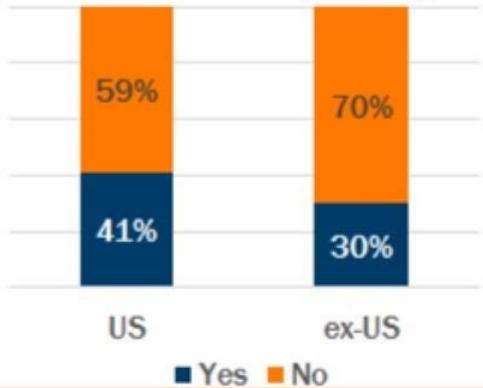Have you ever been diagnosed with depression by your doctor?
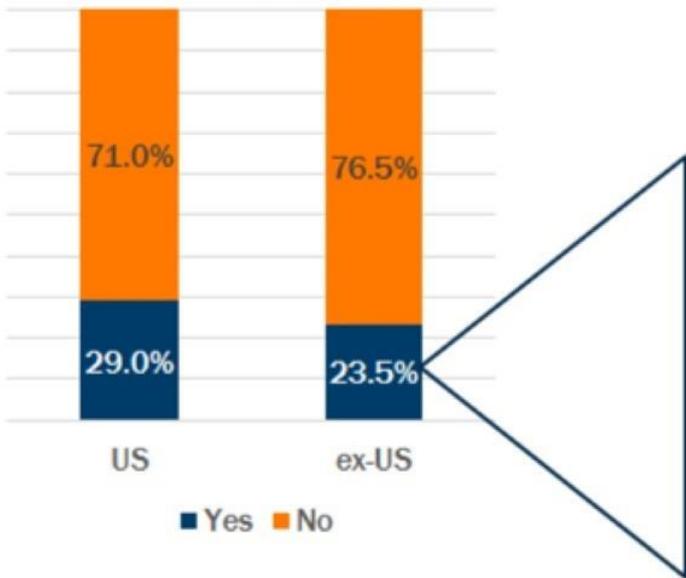
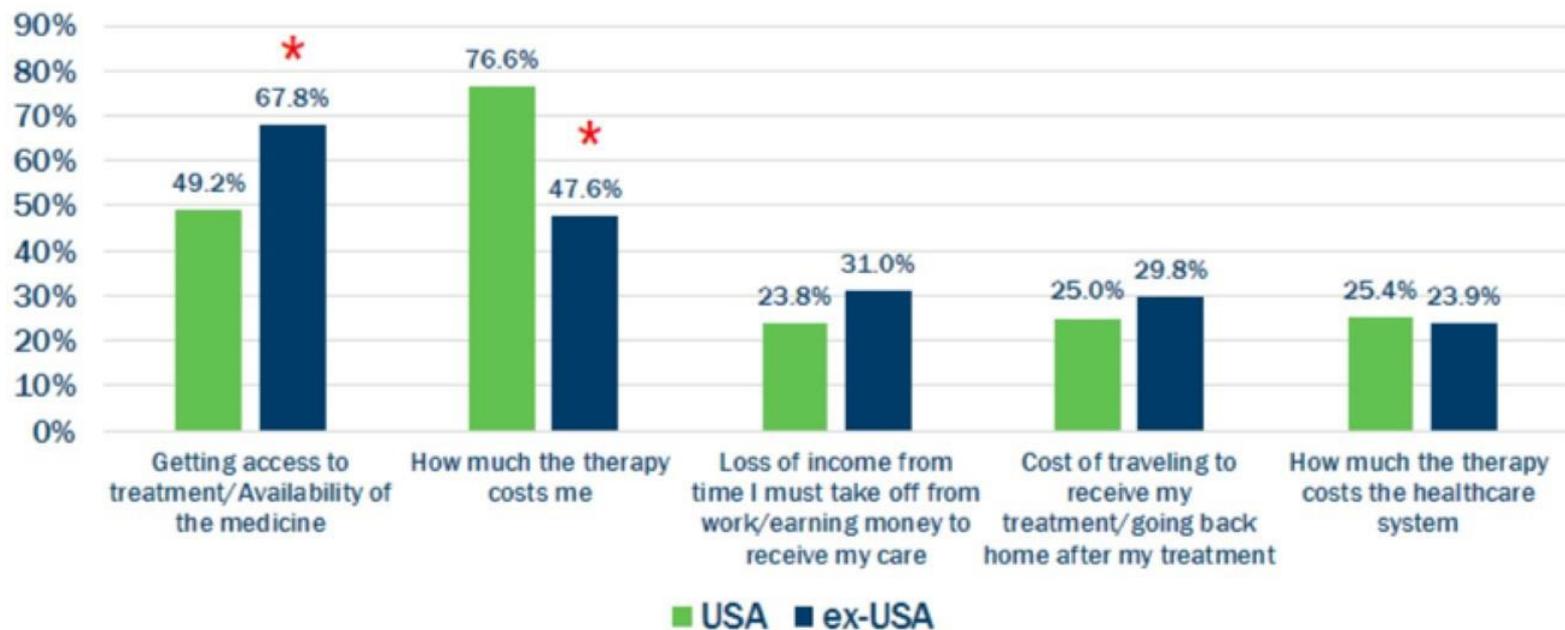Were you diagnosed with depression after your lung cancer diagnosis?

Have you thought about suicide since your lung cancer diagnosis?

FINANCIAL IMPACT OF AN EGFR CANCER DIAGNOSIS

What are your main concerns when it comes to the cost of cancer care?

* = P <0.05 by chi-square test, respondents ranked top concerns from 1 to 5 where 1 = top concern and 5 = least concern

N = 350

CONCLUSIONS

- Project PRIORITY participants match characteristics of the EGFR-positive lung cancer community

- An EGFR lung cancer diagnosis significantly impacts the quality of life, as evidenced by:
  - High rates of hospitalization
  - Depression
  - Financial toxicity associated with treatment

- Additional analysis ongoing:
  - Risk factors including familial history of lung cancer
  - Biomarker testing
  - Treatment sequencing (including clinical trial participation) and side-effect management

Patient-reported data is a powerful source of real-world data and can complement clinician-reported data and electronic health records data to identify treatment patterns

IN MEMORIAM

Anita Figueras
Co-founder, EGFR Resisters

Teri Kennedy
Co-founder, EGFR Resisters