UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): April 20, 2017

XBIOTECH INC.

(Exact name of Registrant as specified in its charter)

British Columbia, Canada
(State of Incorporation)

001-37347
(Commission File Number)

N/A
(I.R.S. Employer Identification No.)

8201 E Riverside Dr. Bldg 4, Ste 100
Austin, Texas
(Address of principal executive offices)

78744
(Zip Code)

(512) 386-2900
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)
Emerging growth company ý

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Outcome of EMA Oral Explanation Meeting

On April 20, 2017, XBiotech Inc. (the “Company”) issued a press release announcing the outcome of its Oral Explanation meeting (“OE”) to discuss its Day 180 List of Outstanding Issues related to the Company’s Marketing Authorization Application submission for its lead product candidate in Europe. The Company reported that the European Medicines Agency (“EMA”) rendered a negative “trend” vote after the meeting, making a positive Committee for Medicinal Products for Human Use (“CHMP”) opinion unlikely. At the OE the Company gave a 20 minute presentation and had a Q&A session with CHMP members per standard meeting protocol.

A copy of the press release issued in connection with the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the presenation is filed as Exhibit 99.2 to this Current Report on Form 8-K.

This Form 8-K and the related press release contain forward-looking statements, including declarations regarding management's beliefs and expectations, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “would,” “could,” “expects,” “plans,” “contemplate,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “intend” or “continue” or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in "Risk Factors" in our SEC filings.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number		Description
99.1		Press Release of XBiotech Inc., Issued April 20, 2017.
99.2		Oral Explanation Presentation Slides

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 20, 2017

XBIOTECH INC.

By: /s/John Simard
John Simard
Chief Executive Officer and President

EXHIBIT 99.1

XBiotech Announces Outcome of EMA's Oral Explanation Meeting

AUSTIN, Texas, April 20, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that the European Medicines Agency (EMA) rendered a negative "trend" vote after meeting with the Company to discuss the "Day 180 List of Outstanding Issues" related to the Company's marketing authorization application (MAA) for its candidate antibody for the treatment of colorectal cancer. A negative trend vote means it is unlikely that a positive Committee for Medicinal Products for Human Use (CHMP) opinion related to the Company's MAA will be attained at the formal decision vote scheduled in May, and that additional steps would need to be taken to potentially gain marketing approval.

At the Oral Explanation meeting, per EMA protocol, the Company gave a 20 minute presentation and had a Q&A session with CHMP members regarding the MAA for its candidate therapy to treat advanced colorectal cancer (data presented by the Company will be filed with the SEC in a Form 8-K and will be available on the SEC's website at www.sec.gov). The Oral Explanation format is intended to provide an opportunity for the Company to clarify data in support of marketing authorization.

The key outstanding issues are related to clinical relevance of the therapy in the indication and quality assurance related matters. The meeting, however, focused on outstanding clinical relevance issues.

John Simard, President & CEO of the Company, stated, "We are disappointed by the outcome of the meeting. We believe that the data speak in a clear and resounding voice to clinical relevance of a new antibody therapy in advanced colorectal cancer. We believe that findings from our Phase III study show that we have developed an important endpoint and methodology to evaluate anti-cancer therapy in advanced stage disease and that our monoclonal antibody represents a breakthrough treatment in patients with advanced colorectal cancer. The EMA marketing authorization application procedure enables the appeal of negative decisions from the oral explanation. We may seek access to this process at the appropriate time."

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

About XBiotech
XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technology. XBiotech currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. For more information, visit www.xbiotech.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contact
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512-386-2930

EMA
April 20th 2017

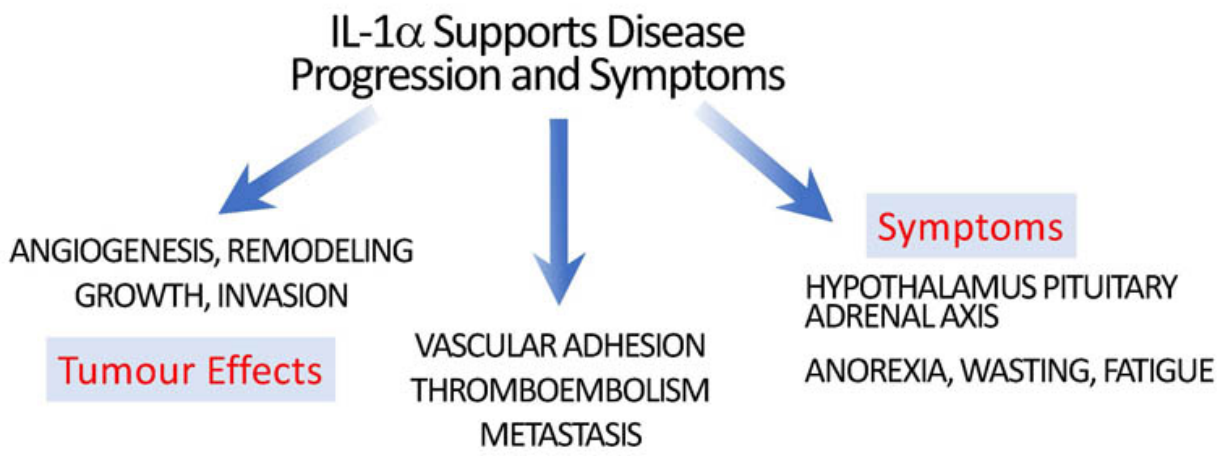
Hutruo Findings

Dr. A. Hendifar MD, MPH

Cedar Sinai Medical Center
UCLA Medical Center

Co-Director Pancreas Cancer & Medical Oncology Lead Gastrointestinal Diseases

HUTRUO Targets Tumour-Related Inflammatory Pathways which Promote Disease Progression and Debilitating Symptoms



New Treatment Approaches Are Needed for Advanced Metastatic Colorectal Cancer Cancer (mCRC)

- Europe Has the Highest Incidence of Refractory mCRC.
- Toxicities of Cytotoxic Drugs Outweigh Benefit in Refractory mCRC.
- Tumour Eradication in mCRC is an Unrealistic Goal.
- Anti-Cancer Therapies without Tumour Eradication (Toxicity) are Possible.
- New Endpoints Are Needed to Evaluate these Potential Breakthrough Therapies.

Far-sighted EMA Guidance Proposes Evaluation of Anti-Cancer Agents based on **Symptom Control**

"**Symptom Control**, if related to Anti-Tumour Effects, is a Valid Measure of Therapeutic Activity and may serve as a Primary Endpoint in Late Line Therapy Studies[1]."

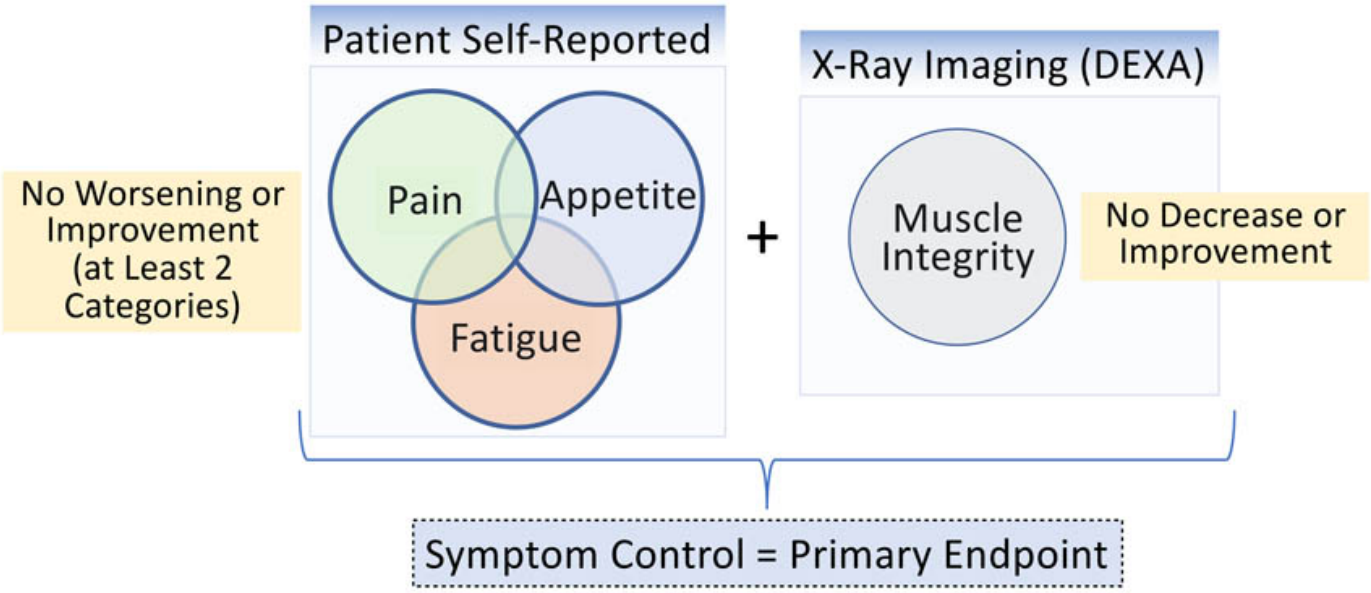
[1]13 December 2012,EMA/CHMP/205/95/Rev.4 Oncology Working Party.

Pain, Fatigue, Appetite, and Muscle Mass were used as Measure of "Symptom Control" in Refractory mCRC

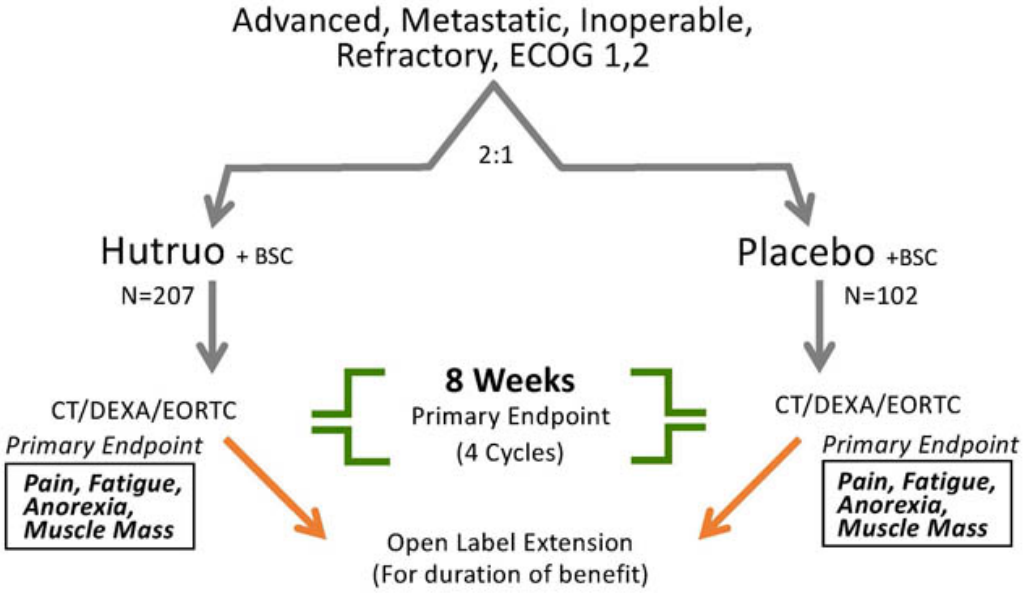
- Hutruo Previously Reported to Provide "Disease Control" in Advanced Cancer Patients—including Relief from Pain, Fatigue, Anorexia; Muscle Mass Recovery; and Anti-Tumour Effects[1]
- Symptoms **COMBINED** into a Primary Endpoint for Use in Pivotal Phase III Study Designed in Collaboration with EMA's Scientific Advice Working Party (SAWP)
- Primary Endpoint was Considered Clinically Important Measure of Disease/Symptom Control

[1]Hong et al. Lancet Oncol. 2014 May;15(6):656-66.

In Pivotal Phase III Study, "Symptom Control" was used to Measure Treatment Response to Hutruo



Pivotal Phase III Study
Double-Blinded, Placebo Controlled



Phase III Study Results
Lancet Oncology:
"A New Standard in the Management of Advanced Colorectal Cancer[1]"

Intent to Treat (mITT) n=309

33% of Patients Receiving Hutruo met Primary Endpoint vs 19% treated with Placebo (p=0.0045)

(relative risk 1.76, 95% CI 1.12-2.76, one-tailed p=0.0045)

Per Protocol (PP) n=252

40% of Patients Receiving Hutruo met Primary Endpoint vs 23% Treated with Placebo (p=0.0033)

(relative risk 1.76, 95% CI 1.14 to 2.72, one-tailed p= 0.0033)

[1]Hickish et al. Lancet Oncol. 2017 Feb;18(2):192-201

Safety
Adverse Events in Hutruo arm are Consistent with Background for the Advanced mCRC Population

"Blinded" Physicians Reported that 9.6% of Adverse Events in Placebo Arm were "possibly, probably or definitely" drug-related.

Only 8.6% of Adverse Events in Hutruo arm were deemed Possibly Drug-Related. [26 of 264 (9.6%) vs 53 of 618 (8.6%), (p=0.61)]

Most Common Grade 3-4 Events			
Event	Hutruo (n=207)	Placebo (n=102)	P value (Fisher's exact)
Anemia	4%	5%	0.76
Fatigue	3%	7%	0.13
Aspartate Aminotransferase	3%	2%	1.00
Alkaline Phosphatase	4%	2%	0.35

Safety
Overall Assessment by Type & Grade

- No Clinically or Statistically Significant Differences in the Incidence of ANY Adverse Event, by Preferred Term or Grade, between Hutruo and Placebo.
- No Deaths were Related to Hutruo. 17 (8%) Patients Died in Hutruo Arm versus 11 (11%) Patients in Placebo over the 8 week Study Period.
- There was a lower incidence of SAEs in the treatment arm 23% (48 of 207) versus placebo 31% (32 of 102), although difference did not reach statistical significance (p=0.069).

Addressing Major Objections Relating to Clinical Efficacy & Quality

Reviewer Statements Related to Clinical Efficacy

"The clinical relevance of this rather small difference in favour of treatment with MABp1 is questioned and not considered compelling."

"Neither the sensitivity analyses of the individual **co-primary** endpoints, nor the analyses of secondary or exploratory endpoints provide any supportive evidence for efficacy in favour of MABp1."

Major Clinical Objections
Clinical Relevance

Statement 1:

"The clinical relevance of this rather small difference in favour of treatment with MABp1 is questioned and not considered compelling."

Response:

- The Primary Endpoint is a Robust and Clinically Relevant Measure of Outcome in mCRC.
- For the 82% of Patients Completing 4 Cycles of Therapy, 40% Achieved Primary Endpoint.
- For Patients in 3rd line Treatment with Limited Options with other cytotoxic or targeted Therapies, most with substantial toxicities, a Significant Difference between Arms of 14-17% for Hutruo is Clinically Relevant and Important to this mCRC Patient Population.

Major Clinical Objections
Sensitivity Analysis

Statement 2:

"Sensitivity analyses of the individual co-primary endpoints (LBM and disease-related QoL symptoms) **did not indicate any statistically significant or clinically relevant differences** between the study arms."

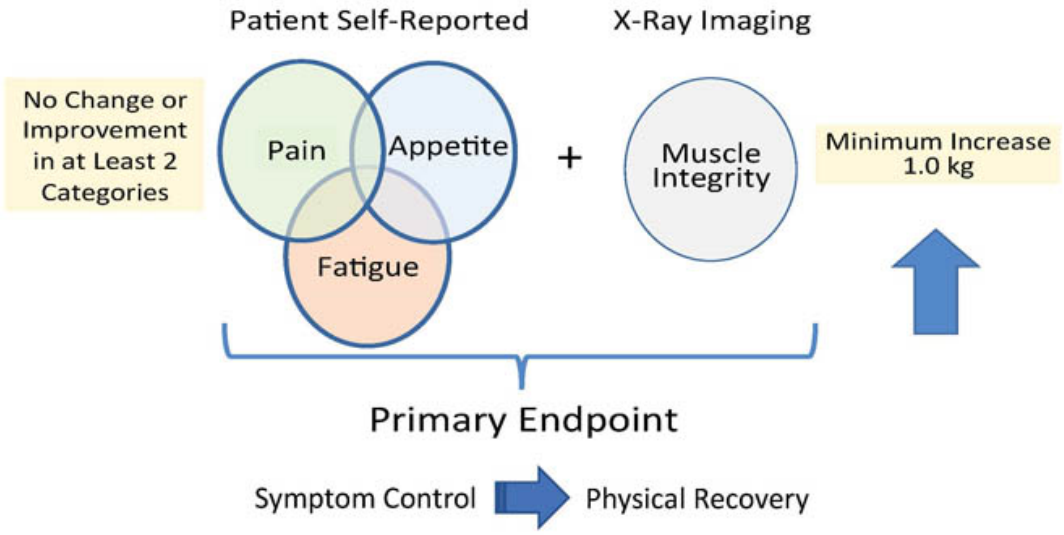
Response: LBM (Lean Body Mass)

Sensitivity Analysis was Performed as requested by the EMA on page 82, List of Outstanding Issues*: "Applicant is asked to provide further analyses for composite [endpoint] (mITT and PP), including only patients with a clinically relevant increase of LBM (e.g. **defined as at least 1 kg increase from baseline to Week 8**) *and* improvement or no worsening of QoL symptoms (2 of 3) of fatigue, appetite and pain."

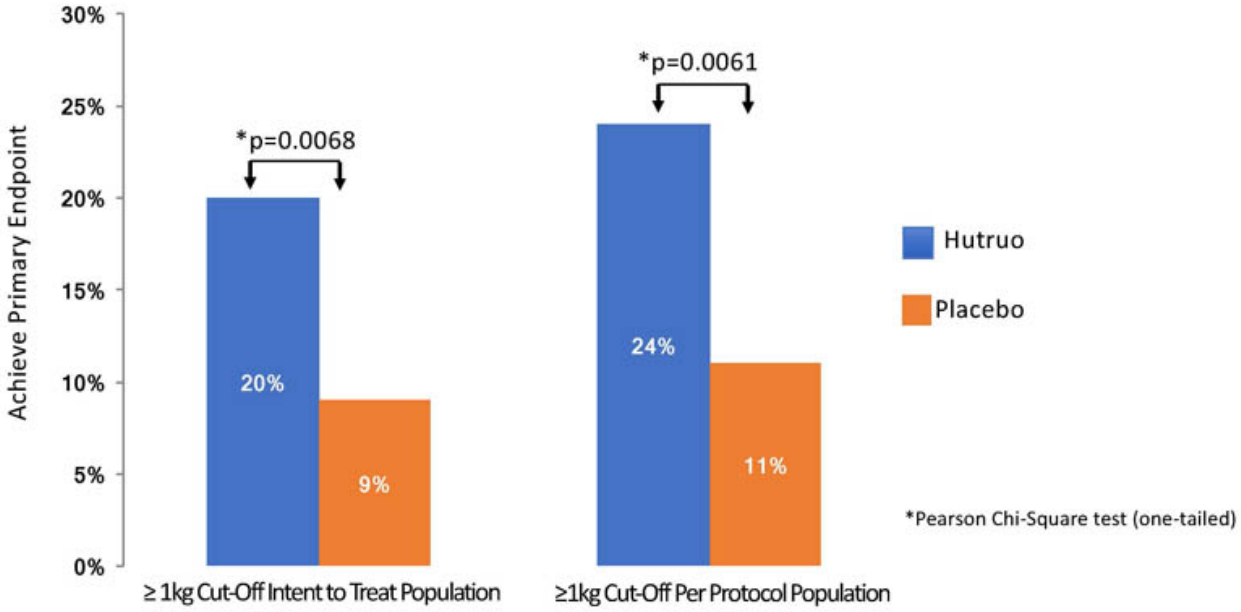
Outcome: **Analyses was Significant using "Clinically Relevant" Differences**.

*London, 15 December 2016, EMA/CHMP/840047/2016 Committee for Medicinal Products for Human Use (CHMP) CHMP Day 180 list of outstanding issues

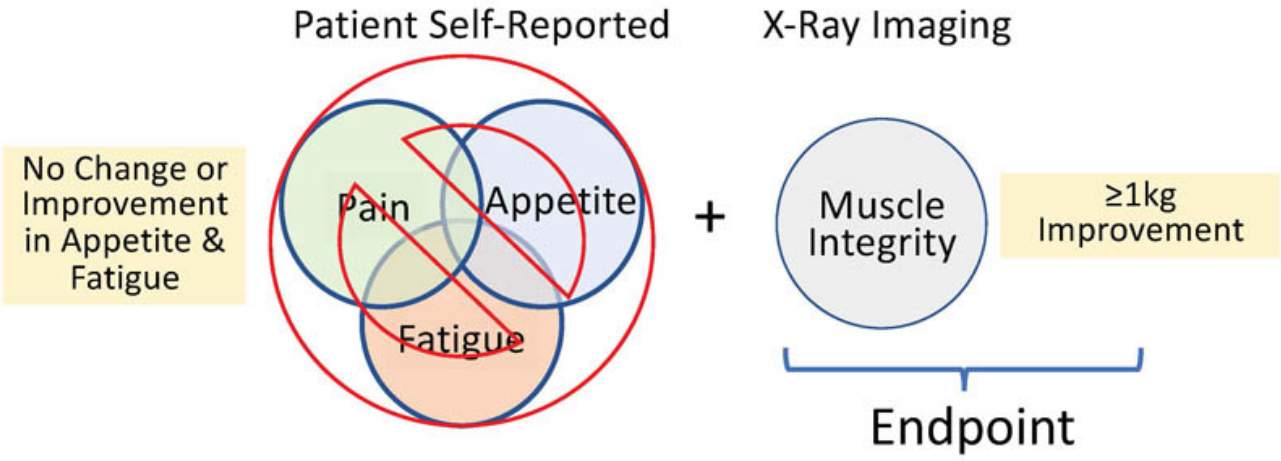
EMA Requested Sensitivity Analysis: At Least 1kg LBM Increase



At Least 1kg LBM Increase: Significant Outcome for Intent to Treat and Per Protocol Populations



Sensitivity Analysis
LBM (Lean Body Mass)
Signficantly More Patients on Hutruo Gained at Least 1 kg LBM



Hutruo 31% (64) vs Placebo 20% (20), (p=0.018)

Sensitivity Analysis
Self-Reported Outcomes

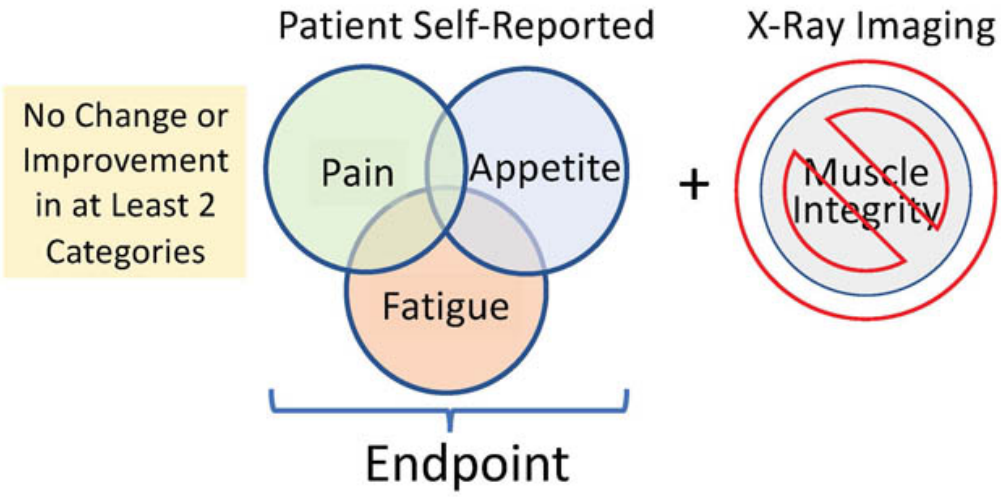
Statement: "Sensitivity analyses of the individual co-primary endpoints (LBM and disease-related QoL symptoms) did not indicate any statistically significant or clinically relevant differences between the study arms."

QoL [Patient Self-Reported Outcomes (EORTC-QLQC30)]

Response: The Self-Reported Outcome Component of the Primary Endpoint was Measured Independently of LBM.

Outcome: Significant Difference Between Hutruo and Placebo arms for Self-reported Outcomes.

Sensitivity Analysis
Individual Measure of Self-Reported Outcomes



Hutruo 51% (106) vs Placebo 30% (40), (p=0.024)

Sensitivity Analysis—Excluding Pain

Statement: "Sensitivity analyses of the individual co-primary endpoints (LBM and disease-related QoL symptoms) did not indicate any statistically significant or clinically relevant differences between the study arms."

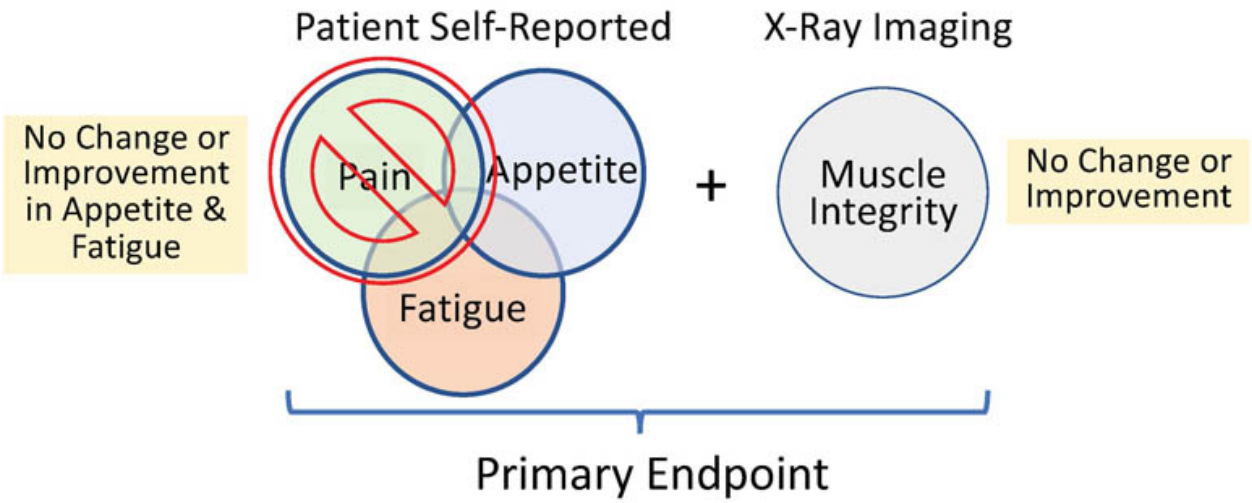
QoL Symptoms: Excluding Pain

Response: EMA Requested in its Day 120 List of Outstanding Issues* that in the Primary Endpoint Analysis Pain should be Excluded from the Self-Reported Measures such that "A sensitivity analysis of the composite [Endpoint] should be performed in the mITT and PP populations, excluding the pain scale, as this particular symptom is subject to high bias due to concomitant use of analgesics."

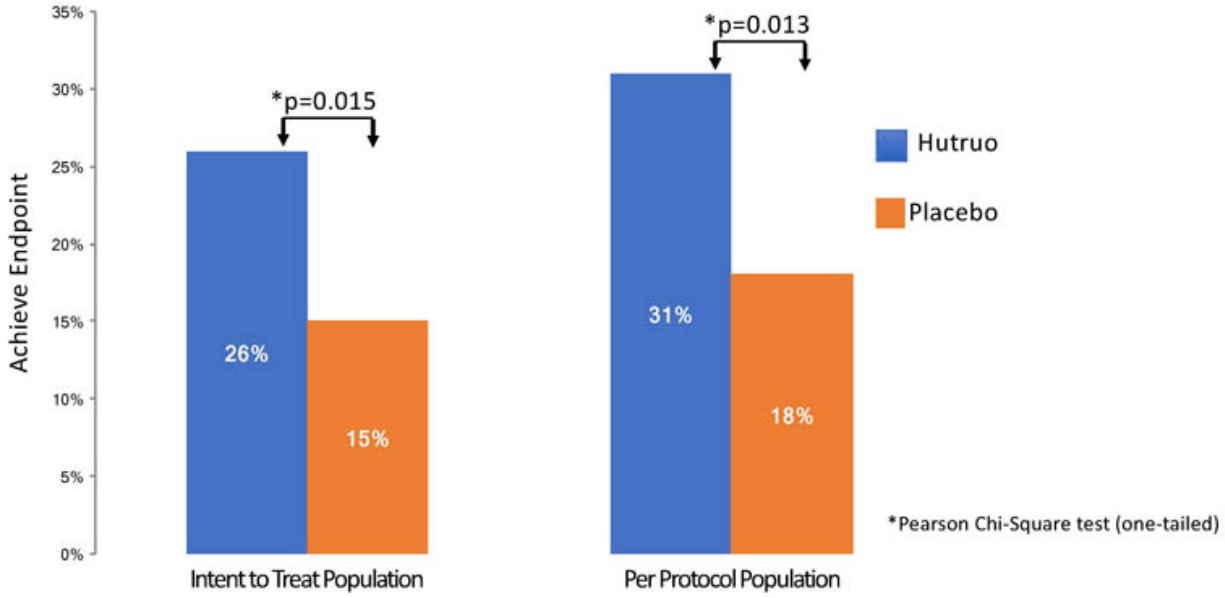
Outcomes: When Excluding Pain the Findings Remained Significant for both mITT and PP Populations

*Pg. 96, Q.220, Day 120LOI, London, 21 July 2016, EMA/CHMP/493139/2016, Committee for Medicinal Products for Human Use (CHMP)

Sensitivity Analysis
Excluding Pain from Self-Reported Outcomes



Primary Endpoint Excluding Pain is Significant



Secondary & Exploratory Endpoints

Statement: **"Secondary or Exploratory** Endpoints do not Provide Any Supportive Evidence for Efficacy in Favour of MABp1."

Response: Secondary and Exploratory Endpoints were as Follows:

Secondary: Hutruo-Related Reduction in Serum IL-6; Control of Paraneoplastic platelet Expansion; and Individual measures of QoL Domain from EORTC between Arms.

Exploratory: Association of Primary Endpoint with Improved Survival; Reduced Tumour Progression; Reduction in Serious Adverse Events (SAEs).

Outcomes: **All Secondary and Exploratory Endpoints Analysis** Provided Significant Outcomes and Supportive Evidence of Efficacy in Favour of Hutruo.

Secondary Endpoint
Interleukin-6 (IL-6)

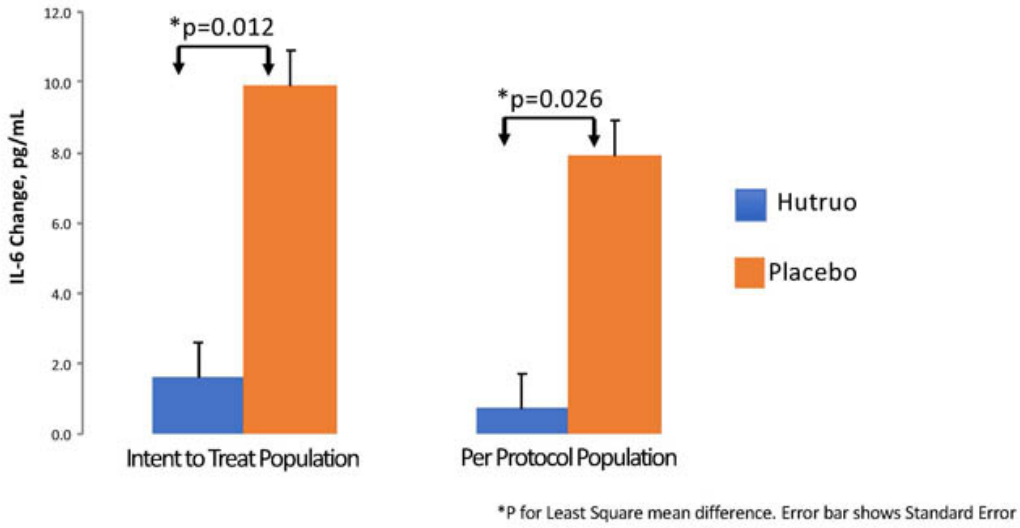
Statement: "Secondary endpoints do not provide any supportive evidence for efficacy."

Background:

1. Hutruo neutralizes interleukin-1α (IL-1α), which is a potent inducer of IL-6 expression.
2. Specific Activity of Hutruo Reduces Serum IL-6 levels.
3. Reduction in Serum IL-6 Demonstrates Biological Activity of Hutruo.
4. Serum IL-6 levels are Prognostic for Survival in Advanced Cancer[1].

[1]Lippitz & Harris, Oncoimmunology, 2016, VOL. 5, NO. 5, e1093722

Secondary Endpoint
Hutruo **Significantly Reduces** Serum IL-6 Levels for Intent to Treat and Per Protocol Populations



*P for Least Square mean difference. Error bar shows Standard Error

Decreasing Serum IL-6 Levels Associated with Survival

Change in IL-6 Serum Levels (pg/ml)	N	Death %	Median Survival (95% CI), months	HR (95% CI)	Log-rank p
Decreased	53	68%	8.6 (6.8 to 10.1)	1.65 (1.11 to 2.45)	0.013
Increased	99	79%	5.2 (4.2 to 7.2)		

Secondary Endpoint
Paraneoplastic Platelet Expansion

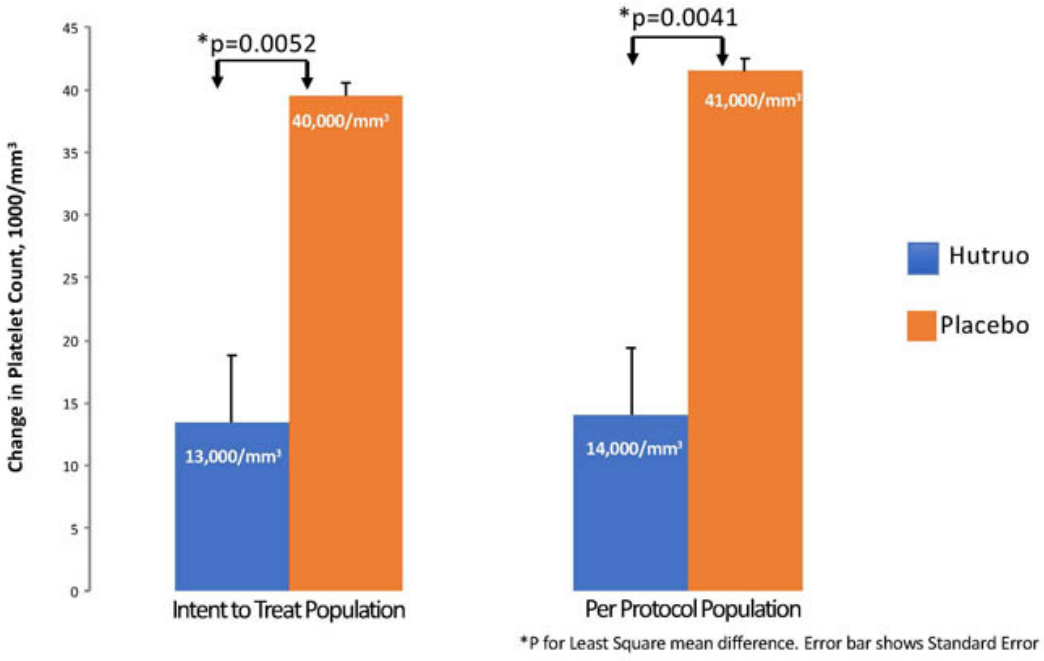
Statement: "Secondary endpoints do not provide any supportive evidence for efficacy."

Background:

1. Platelet Production from Megakaryocyte is regulated by interleukin-1α.
2. Specific Activity of Hutruo Reduces Paraneoplastic Expansion of Platelet Counts.
3. Platelet Counts were observed as a measure of Hutruo activity.
4. Platelet Counts are also Prognostic for Survival in Advanced Cancer[1].

[1]Arterioscler Thromb Vasc Biol . 2010 December ; 30(12): 2362–2367.

Secondary Endpoint—Platelets
Hutruo **Significantly Reduces** Neoplastic Expansion of Platelet Counts



*P for Least Square mean difference. Error bar shows Standard Error

Secondary Endpoints—QoL

Statement: "There is **no correlation to any meaningful changes for the QoL** for the subjects in the pivotal study."

Response:

- The Combined Patient Self-Reported Quality of Life Outcomes used in the Primary Endpoint Did in Fact Improve in the Hutruo Compared to Placebo arms.
  [51% (106) vs Placebo 30% (40), (p=0.024)].
- The Individual QoL Domain Improved in subjects Achieving the Primary Endpoint
  [+4.3 vs -7.0 score points (p<0.0001)].
- The QoL Domain Supports the Clinical Relevance of the Primary Endpoint.

Exploratory Endpoints
Tumour Response

Statement: "There is **no evidence** in support of clinically relevant efficacy from Exploratory Endpoints."

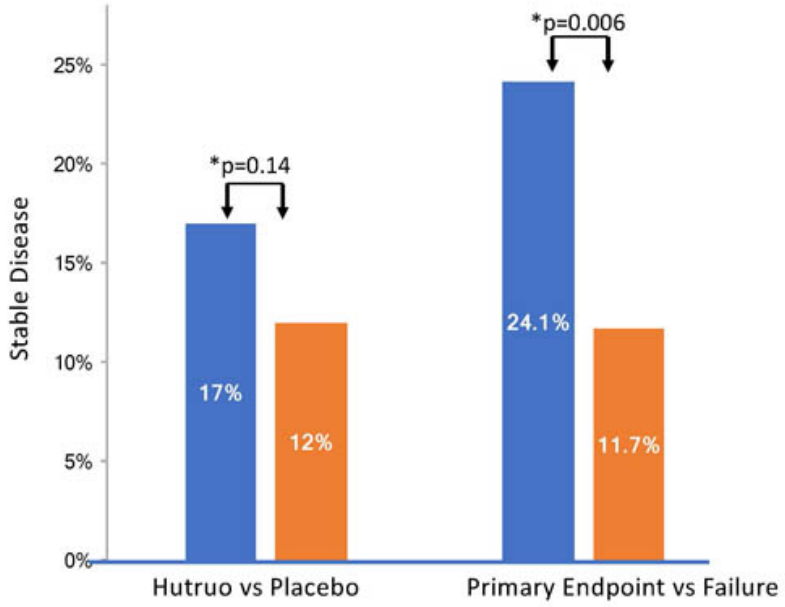
Objective Tumour Response

Background: Hutruo Blocks Inflammatory Pathways Support Tumour Growth and Metastasis (Neoangiogenesis, Tissue Matrix (stromal), Paraneoplastic Thrombocytosis, Metabolic Dysregulation).
RECIST Measure was made from Baseline and after 8 weeks of Therapy to Evaluate Objective Tumour Response.

Response: Tumour Measure was an Exploratory Endpoint, i.e. was Not Powered for Statistical Significance.

Outcomes: Hutruo Treated Patients Showed Trend Toward Arrest of Tumour Growth. The Primary Endpoint was Significantly Associated with Reduced Tumour Growth.

Trend Toward Reduced Tumour Growth in Hutruo Treated Patients & Significant Reduction in Patients Meeting Primary Endpoint



Exploratory Endpoints
Clinical and Biological Outcomes Support Clinical Relevance of Primary Endpoint

Improvements Observed	Significance
Global QoL	p<0.0001
Physical Function	p<0.0001
Role Function	p<0.0001
Emotional Function	p<0.0001
Social Function	p<0.0001
Fatigue	p<0.0001
Pain	p<0.0001
Paraneoplastic Platelets	p=0.00017
Systemic Inflammation (IL-6)	p=0.00071
Lean Body Mass (kg) 1.4 kg	p=0.00044
Serious Adverse Events (80% Reduction)	p=0.001
Tumour Progression Risk (50% Reduction)	p=0.0062
Overall Survival* (11.5 Months vs 4.2)	p<0.001

*Kaplan-Meier analysis was used to compare overall survival of subjects achieving the primary endpoint with those that failed to achieve the endpoint. Subjects achieving the primary endpoint had a median survival of 11.5 months versus 4.2 months for progressors (Hazard ratio 0.31, 95% CI 0.20 to 0.48, p<0.001).

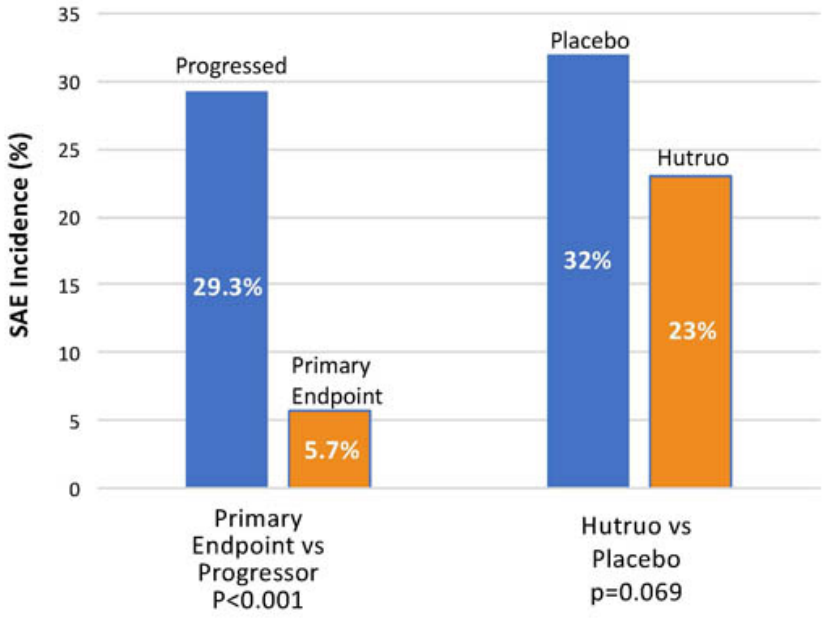
Major Clinical Objections
Safety

Statement: "Safety Database is Currently Limited, both Regarding Total Number of Patient Population and Duration of Treatment."

Response:

- Hutruo Demonstrated **First-in-Class** Safety in 700 Patients (and Several Thousand Doses of **Hutruo**).
- 3 Months Median Duration of Exposure was achieved in the Phase III study in a Patient Population with an Expected Median Overall Survival of only 4-5 months.
- Duration of Exposure is a Substantial Portion of Expected Life Span.

Safety
Reduction in SAEs—Trend in Hutruo Arm



For the 19 Most Recently Approved Anti-Cancer Agents, Overall a 77% Increase in AEs Over Comparators was Reported[1].

Niraula et al. J. Clin. Oncology 2014 Vol 32;32

Safety

Statement:

"An increased number of infections (including serious infections) was observed in MABp1–treated patients compared to placebo."

Response:

1. Not a Single Infection or Serious Infection was Reported by Investigators to be Related to Hutruo Therapy.
2. No Significant Difference in Number of Infections (12% vs 9%, p=0.44) or Serious Infections (3% vs 1%, p=0.43) in Hutruo vs Placebo.
3. For 6 SAE Infections that Occurred in Hutruo treatment arm, ALL were Deemed Related to Disease Progression.
4. All But 1 Case Resolved with Antibiotics and Patients Continued to Receive Hutruo Therapy.
5. No Infections Related to Hutruo.

Case Report Summaries for Serious Infections

Case	Description	Comments	Outcome
1.	Upper respiratory tract infection	Cough and subjective fever in a patient with bilateral pulmonary metastatic lesions, left upper lobe lobectomy and a history of multiple pulmonary emboli. No demonstration of acute infectious process, including normal chest x-ray, normal white count and no measurable fever.	**Continued Hutruo**
2.	Ileus and Peritonitis	Peritonitis occurring after insufficient bowel resection for disease progression, which resulted in leakage of bowel contents.	**Died**
3.	"Pneumonia"	Clinically suspected pneumonia in a patient with multiple pulmonary metastases presenting with dyspnea and fever with proven urinary tract infection secondary to nephrostomy.	**Continued Hutruo**
4.	Urosepsis	Bacteriuria and bacteremia in a patient with obstructive pathology of the urinary tract. Percutaneous nephrostomy required in addition to antibiotics.	**Continued Hutruo**
5.	Pyonephrosis	Kidney infection in patient with obstructive pathology of the urinary tract. A nephrostomy was required in addition to antibiotics.	**Continued Hutruo**
6.	"Pneumonitis"	Right middle lobe pneumonia in a patient with multiple pulmonary metastases.	**Continued Hutruo**

Safety Data with Other Agents to Treat mCRC

- In a Phase III Study in 760 patients, Regorafenib had a 1% objective Response Rate while 93% of patients had Drug-Related Toxicities[1].

- A Pivotal Study for TAS-102 in mCRC showed a Tumour Response Rate of 1.6%— with 69% of Patients Experiencing Grade 3 or Higher Drug-Related Adverse Events[2].

[1]Grothey, A. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial. Lancet. 2013 Jan 26;381(9863):303-12.

[2]Mayer RJ, et al. Randomized trial of TAS-102 for refractory metastatic colorectal cancer. N Engl J Med. 2015 May 14;372(20):1909-19. doi: 10.1056/NEJMoa1414325.

Hutruo Fills an Unmet Need in Refractory mCRC

- Hutruo Targets Tumour Inflammatory Pathways Involved in Disease Progression and Debilitating Symptoms.
- Hutruo Inhibits Tumour without Collateral Toxicity on Healthy Tissue.
- Combined Endpoint—Pain, Fatigue, Appetite, and Lean Mass—is an Important and Relevant Measure of Clinical Performance.
- Hutruo Demonstrated First-In-Class Safety.
- Hutruo has a Positive Benefit-Risk Profile in mCRC.