
Section 1: 8-K (8-K)

**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): November 22, 2019

Zymeworks Inc.

(Exact name of registrant as specified in its charter)

British Columbia, Canada
(State or other jurisdiction
of incorporation)

001-38068
(Commission
File Number)

47-2569713
(IRS Employer
Identification No.)

Suite 540, 1385 West 8th Avenue, Vancouver, British Columbia, Canada
(Address of principal executive offices)

V6H 3V9
(Zip Code)

(604) 678-1388

(Registrant's telephone number, including area code)

Not Applicable

(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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Shares, no par value per share	ZYME	New York Stock Exchange

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

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

On November 22, 2019, Zymeworks Inc. (“Zymeworks”) issued a press release announcing updated Phase 1 data for single agent ZW25 in heavily pretreated patients with HER2-expressing solid tumors in a mini oral presentation by Dr. Do-Youn Oh, study investigator and Professor at Seoul National University, at the ESMO Asia 2019 Congress, taking place November 22—24 in Singapore.

On November 22, 2019, this press release was filed with the Canadian securities regulatory authorities in Canada on the System for Electronic Document Analysis and Retrieval (“SEDAR”) at www.sedar.com. Additionally, on November 22, 2019, Zymeworks filed a material change report regarding this matter with the Canadian securities regulatory authorities on SEDAR at www.sedar.com. Copies of this press release and material change report are respectively filed as exhibits 99.1 and 99.2 hereto.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 22, 2019.
99.2	Material Change Report dated November 22, 2019.

SIGNATURES

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

ZYMEWORKS INC.

(Registrant)

Date: November 22, 2019

By: /s/ Neil A. Klompas
Name: Neil A. Klompas
Title: Executive Vice President, Business Operations and Chief Financial Officer

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Section 2: EX-99.1 (EX-99.1)

Exhibit 99.1



Zymeworks Highlights Advancing Clinical Collaboration with BeiGene and Updated ZW25 Phase 1 Data in HER2-Expressing Cancers at ESMO Asia Congress

Singapore (November 22, 2019) – Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, today announced updated Phase 1 data for single agent ZW25 in heavily pretreated patients with HER2-expressing solid tumors in a mini oral presentation by Dr. Do-Youn Oh, study investigator and Professor at Seoul National University, at the ESMO Asia 2019 Congress, taking place November 22—24 in Singapore. Zymeworks and its collaborator BeiGene, Ltd. plan to advance ZW25 into potentially registration-enabling global studies in HER2-expressing biliary tract cancer (BTC) and gastroesophageal adenocarcinoma (GEA), based on these durable and consistent clinical data.

“The promising ZW25 data at ESMO Asia further build momentum for the expanding footprint of our ZW25 clinical development program with BeiGene,” said Ali Tehrani, Ph.D., President and CEO of Zymeworks. “Cancer is a global fight, and this strong collaboration helps us to rapidly execute on upcoming late-stage studies for people with HER2-expressing cancers worldwide.”

“The encouraging clinical data on ZW25 supports further evaluation of this bispecific antibody in HER2-expressing solid tumors,” said John V. Oyler, Co-Founder, CEO, and Chairman of BeiGene. “We’re enthusiastic about the meaningful progress of ZW25 since we established the collaboration with Zymeworks one year ago and look forward to leveraging our unique strengths and expertise to advance ZW25 clinical development globally.”

The updated single agent results of the ongoing Phase 1 trial of ZW25 in patients with HER2-expressing solid tumors include additional safety and anti-tumor activity data from those presented at the ESMO 2019 Congress.

ZW25 Clinical Results Presented Today

Safety, Anti-Tumor Activity, and Biomarker Results of the HER2-Targeted Bispecific Antibody ZW25 in HER2-Expressing Solid Tumors (Presentation# 610, Mini Oral on Friday, November 22 at 3:30 pm SGT)

Data were reported from 69 patients diagnosed with HER2-expressing solid tumors other than breast cancer who received ZW25 at the recommended dose of either 10 mg/kg weekly or 20 mg/kg every other week. Overall, patients received a median of three prior systemic therapies. Those with BTC, GEA, and colorectal cancer (CRC) received a median of 4.5, 3, and 5.5 prior systemic therapies, respectively. Forty-one (59%) patients received prior HER2-targeted therapies, including 93% of GEA patients. Eleven patients were diagnosed with BTC, 28 with GEA, 14 with CRC, and 16 with other HER2-expressing cancers, including endometrial, ovarian, pancreatic, and salivary gland.

Fifty-seven of 69 patients were response evaluable at the time of data cut-off. Overall, the disease control rate (DCR) was 70%, comprising 25 (44%) partial responses and 15 (26%) with stable disease, and 18 (32%) patients experienced disease control for greater than six months. In the nine evaluable biliary tract cancer patients, the DCR was 78%, and the objective response rate (ORR) was 67%. In the 13 CRC and 23 GEA patients, ORRs were 46% and 39%, respectively. Notably, confirmed responses were seen across additional tumor types, including a 100% decrease in target lesions in a patient with pancreatic cancer. The overall median progression-free survival was 5.5 months and is still evolving.

Among all patients, ZW25 was well tolerated as an outpatient therapy. The most common treatment-related adverse events (TRAE) were diarrhea (43%), infusion-related reaction (26%), and nausea (13%). All TRAEs were Grade 1 or 2.

About the Phase 1 Clinical Trial

Zymeworks' Phase 1 study has three parts. From part one of the study (the dose-escalation phase), the recommended single-agent dose was determined to be 20 mg/kg once every two weeks or 10 mg/kg weekly. In the second part of the study (the cohort expansion phase), additional patients are being enrolled to further assess ZW25's single-agent tolerability and anti-tumor activity against a variety of cancer types in different settings. The third part of the study (the combination phase) is underway and evaluating ZW25 in combination with selected chemotherapy agents in gastroesophageal and breast cancer patients with HER2 high or lower HER2 expression levels. More information about ZW25 clinical trials can be found at clinicaltrials.gov.

About ZW25

ZW25 is being evaluated in Phase 1 and Phase 2 clinical trials across North America and South Korea. It is a bispecific antibody, based on Zymeworks' Azymetric™ platform, that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. This unique design results in multiple mechanisms of action including dual HER2 signal blockade, increased binding and removal of HER2 protein from the cell surface, and potent effector function leading to encouraging anti-tumor activity in patients. Zymeworks is developing ZW25 as a HER2-targeted treatment option for patients with any solid tumor that expresses HER2. The FDA has granted Fast Track designation to ZW25 for first-line gastroesophageal adenocarcinoma in combination with standard of care chemotherapy and Orphan Drug designation to ZW25 for the treatment of both gastric and ovarian cancers.

About Zymeworks Inc.

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Zymeworks' suite of therapeutic platforms and its fully integrated drug development engine enable precise engineering of highly differentiated product candidates. Zymeworks' lead clinical candidate, ZW25, is a novel Azymetric™ bispecific antibody currently in Phase 2 clinical development. Zymeworks' second clinical candidate, ZW49, is a bispecific antibody-drug conjugate currently in Phase 1 clinical development and combines the unique design and antibody framework of ZW25 with Zymeworks' proprietary ZymeLink™ cytotoxic payload. Zymeworks is also advancing a deep preclinical pipeline in immunoncology and other therapeutic areas. In addition, its therapeutic platforms are being leveraged through strategic partnerships with nine biopharmaceutical companies. For more information, visit www.zymeworks.com.

Cautionary Note Regarding Zymeworks' Forward Looking Statements

This press release includes “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and “forward-looking information” within the meaning of Canadian securities laws, or collectively, forward-looking statements. Forward-looking statements in this news release include statements that relate to ZW25 and its potential as an anti-cancer treatment, Zymeworks' clinical plans and future results, Zymeworks' technology platform, and other information that is not historical information. When used herein, words such as “believe”, “may”, “plan”, and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Zymeworks' current expectations and various assumptions. Zymeworks believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Zymeworks may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various factors, including, without limitation, market conditions and the factors described under “Risk Factors” in Zymeworks' Quarterly Report on Form 10-Q for the three month period ended September 30, 2019 (a copy of which may be obtained at www.sec.gov and www.sedar.com). Consequently, forward-looking statements should be regarded solely as Zymeworks' current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. Zymeworks cannot guarantee future results, events, levels of activity, performance, or achievements. Zymeworks does not undertake and specifically declines any obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances, or to reflect the occurrences of unanticipated events, except as may be required by law.

Contacts:

Investor Inquiries:
Ryan Dercho, Ph.D.
(604) 678-1388
ir@zymeworks.com

Tiffany Tolmie
(604) 678-1388
ir@zymeworks.com

Media Inquiries:
Kavita Shah, Ph.D.
(604) 678-1388
media@zymeworks.com

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Section 3: EX-99.2 (EX-99.2)

Exhibit 99.2

FORM 51-102F3 MATERIAL CHANGE REPORT

Item 1: Name and Address of Company

Zymeworks Inc. (“Zymeworks” or the “Company”)
1385 West 8th Avenue, Suite 540
Vancouver, BC, Canada
V6H 3V9

Item 2: Date of Material Change

November 22, 2019

Item 3: News Release

A news release announcing the material change was disseminated through the facilities of Business Wire on November 22, 2019 and a copy was filed on the Company's profile at www.sedar.com.

Item 4: Summary of Material Change

On November 22, 2019, Zymeworks announced updated Phase 1 data for single agent ZW25 in heavily pretreated patients with HER2-expressing solid tumors in a mini oral presentation by Dr. Do-Youn Oh, study investigator and Professor at Seoul National University, at the ESMO Asia 2019 Congress, taking place November 22—24 in Singapore. Zymeworks and its collaborator BeiGene, Ltd. plan to advance ZW25 into potentially registration-enabling global studies in HER2-expressing biliary tract cancer (BTC) and gastroesophageal adenocarcinoma (GEA), based on these durable and consistent clinical data.

Item 5: Full Description of Material Change

5.1 Full Description of Material Change

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5.2 Disclosure of Restructuring Transactions

Not applicable.

Item 6: Reliance on subsection 7.1(2) of National Instrument 51-102

Not applicable.

Item 7: Omitted Information

Not applicable.

Item 8: Executive Officer

For further information, please contact Neil Klompas, Executive Vice President, Business Operations and Chief Financial Officer of the Company at (604) 678-1388.

Item 9: Date of Report

November 22, 2019

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