PHM361H1: Latest Developments in Drugs and Biologics
A Selective Course for Professional Pharmacy Students
Leslie Dan Faculty of Pharmacy
University of Toronto

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Course Description. The course will cover all aspects of new drugs and biologics approved in the preceding 12-month period, together with those that entered phase III clinical trials during the same period. This is a unique course that will discuss the latest in new drugs and biologics. Lectures will be delivered using traditional methods, covering new drugs; pharmacy student groups will present their projects in new drugs and biologics. Instruction materials and the reference materials will be drawn from Health Canada, FDA, scientific literature and drug information files.

Course organization.
First day of classes: Monday January 5, 2015
Last day of classes: Friday April 10, 2015
26 Lectures (13 weeks)

Office hours: Tuesdays 3:30-4:30 PM, Rm# PB-1201 (12th floor, Pharmacy building)

Class hours: Tuesdays 1:30-3:30, Rm# PB-B250 (except on March 6; Time: 11:00 a.m. to 1:00 p.m. in KP 108, Koffler House)
January 6, 13, 20, 27
February 3, 10, 17, 24
March 3, 6, 17, 24, 31
April 7

Assessments.
February 11, 2015 (Wed): Mid-term test (2 hrs; 30% of total grade); Short-written and descriptive written answers; 6:30-8:30 p.m., Galbraith Building, Rooms 404 & 405 (GB 404 & GB 405), 35 St. George Street

January 27- April 7, 2015: Class presentations by student groups (20% weight)

April, 2015: 1 Final exam (3 hours and 50% of total grade); Short-written and/or descriptive written answers

All scores will be totaled and a letter grade will be assigned at the end of the term. Pass grade is 60%. All other issues will be dealt according to the University of Toronto-Leslie Dan Faculty of Pharmacy academic regulations and policies, and/or as set out in this course policies.

Policy and procedure regarding make-up assignments/examinations.
Students who miss Midterm or FINAL, and who have a valid petition filed with the Registrar’s office will be eligible to complete a make-up examination. The format of this examination will be at
the discretion of the course coordinator, and may include, for example, an oral examination. At the discretion of the course coordinator, the weighting of a subsequent examination or test may be increased to compensate for the missed examination not to exceed 80% of the grade, and a make-up exam may not be scheduled.

**Missed Presentation Policy:** Students who miss the class presentation for their group and who have a valid petition on file with Registrar’s office will be eligible to complete a makeup presentation. The presentation topic and format will be determined at the discretion of the course co-ordinator. This presentation will be delivered to the course co-ordinator.

**Late Assignment Policy:** N/A

**Text books:**

**Reference books and journals:**
- http://www.fda.gov
- Goodman and Gilman’s Pharmacological Basis for Therapeutics

**Course Calendar.**

**January**

6 (Tue) -Introduce the course contents, format of the course, and reference materials; introduce the new drugs/biologics to be discussed in the class; student groups formation, assignments to student groups to conduct in-depth research on one scientific aspect /case study.

- Lecture: Small molecule discovery process and Protein therapeutics

13 (Tue) Lecture: Protein therapeutics; Similarities and differences in the discovery and use of biopharmaceuticals and small molecule chemotherapeutics

20 (Tue) Case studies; Discussion on (i) Targeting HER2 by monoclonal antibodies for cancer therapy, and (ii) Discovery of the cholesterol absorption inhibitor, ezetimibe

27 (Tue) Student Presentations

**February**

3 (Tue) Student Presentations

10 (Tue) Student Presentations and Review for Mid-Term

11 (Wed) **MIDTERM EXAM; 6:30-8:30 p.m., Galbraith Building, Rooms 404 & 405 (GB 404 & GB 405), 35 St. George Street; Note:** Mid-term exam will test on the content upto and including Feb 3.

17 (Tue) **READING WEEK – NO CLASS**
24 (Tue)  Student Presentations

March
3 (Tue)  Student Presentations
6 (Fri)  Student Presentations; Time: 11:00 a.m. to 1:00 p.m. in KP 108, Koffler House.
(Make-up class for the pain week miss)
10 (Tue)  **NO CLASS – PAIN WEEK**
17 (Tue)  Student Presentations
24 (Tue)  Student Presentations
31 (Tue)  Student Presentations

April
7 (Tue)  Student Presentations/ Review Session and Questions

To be scheduled:  **FINAL EXAM (50%); NOTE:** Final exam will test on the contents from Jan 6 to, and including April 7.
<table>
<thead>
<tr>
<th>DIN</th>
<th>BRAND/Generic NAME</th>
<th>DOSAGE FORM</th>
<th>COMPANY</th>
<th>APPROVAL DATE</th>
<th>USE</th>
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<tbody>
<tr>
<td>2426862</td>
<td>APTIOM/Eslicarbazepine acetate</td>
<td>TABLET</td>
<td>SUNOVION PHARMACEUTICALS CANADA INC</td>
<td>2014-08-07</td>
<td>A sodium channel blocker for adjunctive treatment of partial-onset seizures.</td>
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<td>2419149</td>
<td>BOSULIF/Bosutinib</td>
<td>TABLET</td>
<td>PFIZER CANADA INC</td>
<td>2014-04-24</td>
<td>A kinase inhibitor for chronic myelogenous leukemia (CML).</td>
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<tr>
<td>2425637</td>
<td>ELELYSO/Taliglucerase Alfa</td>
<td>POWDER FOR SOLUTION</td>
<td>PFIZER CANADA INC</td>
<td>2014-09-08</td>
<td>An enzyme replacement therapy for type 1 Gaucher disease.</td>
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<td>2425696</td>
<td>FIRAZYR/icatibant</td>
<td>SOLUTION</td>
<td>SHIRE ORPHAN THERAPIES INC</td>
<td>2014-07-14</td>
<td>A bradykinin B2 inhibitor used for acute hereditary angioedema.</td>
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<td>2432226</td>
<td>HARVONI/ledipasvir/sofosbuvir</td>
<td>TABLET</td>
<td>GILEAD SCIENCES CANADA INC</td>
<td>2014-10-16</td>
<td>An oral combination product for chronic hepatitis C genotype 1 infection.</td>
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<tr>
<td>2434407</td>
<td>IMBRUVICA/ibrutinib</td>
<td>CAPSULE</td>
<td>JANSSEN INC</td>
<td>2014-11-19</td>
<td>A kinase inhibitor for chronic lymphocytic leukemia.</td>
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<td>2425483</td>
<td>INVOKANA/ canagliflozin</td>
<td>TABLET</td>
<td>JANSSEN INC</td>
<td>2014-06-03</td>
<td>A sodium-glucose co-transporter 2 (SGLT2) inhibitor for type 2 diabetes.</td>
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<td>2420341</td>
<td>JUXTAPID/ lomitapide</td>
<td>CAPSULE</td>
<td>AEGERION PHARMACEUTICALS CANADA LTD</td>
<td>2014-05-06</td>
<td>A microsomal triglyceride transfer protein inhibitor to reduce cholesterol in adults with homozygous familial hypercholesterolemia.</td>
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<td>2419580</td>
<td>POMALYST/ pomalidomide</td>
<td>CAPSULE</td>
<td>CELGENE INC</td>
<td>2014-02-24</td>
<td>A thalidomide analogue for multiple myeloma.</td>
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<td>Application Number</td>
<td>Drug Name/Active Ingredient</td>
<td>Dosage Form</td>
<td>Company</td>
<td>Approved Date</td>
<td>Use</td>
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<tr>
<td>NDA-205718</td>
<td>AKYNZEO/NETUPITANT; PALONOSETRON HYDROCHLORIDE</td>
<td>CAPSULE;ORAL</td>
<td>HELSINN HLTHCARE</td>
<td>2014-10-10</td>
<td>Prevention of acute and delayed nausea and vomiting associated with chemotherapy.</td>
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<td>NDA-204569</td>
<td>BELSOMRA/SUVOREXANT</td>
<td>TABLET;ORAL</td>
<td>MERCK SHARP DOHME</td>
<td>2014-08-13</td>
<td>An orexin receptor antagonist for insomnia.</td>
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<td>NDA-021883</td>
<td>DALVANCE/DALBAVANCIN HYDROCHLORIDE</td>
<td>INJECTABLE;IV (INFUSION)</td>
<td>DURATA THERAPS INTL</td>
<td>2014-05-23</td>
<td>An injectable antibiotic for gram-positive skin infections.</td>
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<tr>
<td>BLA-125476</td>
<td>ENTYVIO/VEDOLIZUMAB</td>
<td>INJECTABLE;INJECTION</td>
<td>TAKEDA PHARMS USA</td>
<td>2014-05-20</td>
<td>Treatment of moderate to severe ulcerative colitis when other medications have not worked well/not tolerated.</td>
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<tr>
<td>NDA-204684</td>
<td>IMPAVIDO/MILTEFOSINE</td>
<td>CAPSULE;ORAL</td>
<td>KNIGHT THERAPS</td>
<td>2014-03-19</td>
<td>Treatment of leishmaniasis in visceral, cutaneous, or mucosal tissues.</td>
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<tr>
<td>NDA-204677</td>
<td>NEURACEQ/FLORBETABEN F-18</td>
<td>SOLUTION;INTRAVENOUS</td>
<td>PIRAMAL IMAGING</td>
<td>2014-03-19</td>
<td>Diagnostic agent used in PET imaging of the brain to estimate β-amyloid neuritic plaque density.</td>
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Components on each drug to be studied/presented:
- Discovery chemistry and pharmacology
- Preclinical toxicology
- Drug formulation
- Phase-I and phase-II studies
- Phase-III studies
- Summary Basis of Decision from Health Canada

Each Group will select one drug. Each student in the group will be responsible for one component on the drug researched by the group, and presenting that component in the class presentation. After each presentation, slides of that presentation will be shared with the entire class and will become reading materials for the class. Final exam will include these materials.

Presentations start on January 27, 2015. Each Group Presentation is for 45 minutes, 7-min each component, and 10 min Q&A from the class.

How to go about learning about these new drugs and each component:
- Health Canada Website: [http://www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)
  - Drugs & Health Products
    - Drug Product Database (DPD)
    - Summary Basis of Decision
- Any other relevant literature