慢性淋巴球白血病社群促請醫院管理局把新一代 BTK 抑制劑納入藥物名冊
為慢淋患者燃點新希望 改善其生活質素

2024 年 6 月 25 日，香港 – 柏臻慈善信託是以支援慢性淋巴球白血病（「慢淋」）社群而獲香港政府認可之慈善團體，今天舉行新聞發佈會，促請香港醫院管理局（「醫管局」）藥物建議委員會把新一代布魯頓氏酪氨酸激酶抑制劑（「新一代 BTK 抑制劑」）納入醫管局藥物名冊及安全網涵蓋範圍。此舉將能為慢淋患者提供多一個治療方案，而且新一代 BTK 抑制劑療效顯著，副作用亦較少，故能在不影響患者生活質素的情況下延長其生存期。

布魯頓氏酪氨酸激酶（「BTK」）是一種蛋白質分子，對促進 B 淋巴球（「B 細胞」）的生長和分化發揮重要的作用。新一代 BTK 抑制劑使用標靶藥物特異性抑制 BTK 分子活性，能中斷細胞訊息的傳遞，阻止癌化 B 總細胞過度增生。因此，新一代 BTK 抑制劑可用於治療華氏巨球蛋白血症及慢性淋巴球白血病等多種淋巴瘤。

慢淋治療的目的是在不影響患者生活質素的情況下提升患者治療反應率、生存期和無惡化存活期。一項由 18 歲以上慢淋患者參與、中位隨訪期為 29.6 個月的臨床試驗，對 652 名復發/難治性慢淋患者提供新一代 BTK 抑制劑及傳統治療標準，以比較兩者療效，發現：

比較新一代 BTK 抑制劑與傳統治療標準對復發/難治性慢淋患者的療效

18 歲以上患者	惡化和死亡的風險	減低 35%
	治療反應率	上升 9.3%
	心臟副作用	減低 8.3%
	脫靶效應	減少
	中斷治療	減少
	心臟疾病發生率	減低
18 歲以上高風險患者	惡化和死亡的風險	減低 47%
	治療反應率	上升 9.3%

另一項以 65 歲以上或有合併症的初治慢淋患者比較新一代 BTK 抑制劑與化學免疫治療的臨床試驗發現：

比較新一代 BTK 抑制劑與化學免疫治療對初治慢淋患者的療效

惡化和死亡的風險	減低 58%

柏臻慈善信託創辦人張榮峰表示：「慢淋是一種通常無法治癒且生長緩慢的血癌，在 50 歲以上的成年人中發病率較高，需要採取細緻入微的治療方法。新一代 BTK 抑制劑為患者提供一個持續治療的選擇，對患者來說十分重要。與許多癌症一樣，慢淋有可能對治療產生抗藥性，故此能夠提供持續治療方案，對於那些對初始治療產生抗藥性、不適合限時治療的患者，或是希望按照生活方式和喜好選用長期治療方案的患者來說，都甚為關鍵。因此，我們促請醫院管理局將新一代 BTK 抑制劑納入藥物名冊及安全網涵蓋範圍，確保所有患者都能獲得最好的治療，不論其病情如何。」

血液及血液腫瘤科專科醫生廖崇瑜醫生表示：「在 2021 年，香港白血病新症數目共有 721 人，每 10 萬人中發病率為 6.5，兩者均較往年上升。雖然慢淋在華人中發生率較低，但其生物學、遺傳學和香港患者的治療結果尚未進行全面研究。值得注意的是，慢淋的臨床表現是多樣化的，大多數患者在診斷時無症狀，多數在例行血液檢查中發現。新一代 BTK 抑制劑能延長生存期以及無惡化存活期、對心臟影響少 8.3%以及具較低中斷治療發生率，顯著改善患者的生活質素。相比傳統治療標準，新一代 BTK 抑制劑用於所有患者和高風險患者，分別減少惡化和死亡的風險 35%和 47%。」

慢淋是白血病的一種，在眾多白血病當中，此症佔當中 25%。其成因是惡性 B 淋巴細胞於骨髓中間被佔據，然後由骨髓蔓延至血液中。骨髓內健康的紅血球、白血球及血小板的增長空間被惡性 B 淋巴細胞佔據，造成貧血和容易出血等問題。慢淋常見的症狀包括頸部、腋下和腹部淋巴結腫脹、腹部飽滯感、肋骨下方疼痛或腫脹、身體無力和長期倦怠、發燒和容易感染、夜間盜汗、出現瘀青和體重下降。

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CLL Community Urges Hospital Authority to List New Generation BTK Inhibitor on Drug Formulary to Bring Hope and Improve Quality of Life for CLL Patients

25 June 2024, Hong Kong – Cypress Charitable Trust, a Hong Kong government approved charity advocating for the betterment of the Chronic Lymphocytic Leukaemia (‘CLL’) community, today hosted a media conference to urge the Hong Kong Hospital Authority (‘HA’) Drug Advisory Committee to list the next generation Bruton tyrosine kinase inhibitor (‘BTKi’) on the HA Drug Formulary with safety net coverage. Adding the new generation BTKi to the suite of therapies available through the HA will give CLL patients access to more options in their treatment regimen, while the new generation BTKi’s efficacious treatment approach and fewer side effects will allow patients an improved survival outcome without compromising their quality of life.

Bruton tyrosine kinase ('BTK') is a protein molecule that plays an important role in promoting the growth and differentiation of B lymphocytes ('B cells'). The use of targeted drugs to specifically inhibit the activity of BTK molecules can interrupt the transmission of cell messages and prevent the excessive proliferation of cancerised B cells. Therefore, the new generation BTKi can be used to treat various lymphomas such as Waldenstrom's macroglobulinemia (WM) and Chronic lymphocytic leukaemia (CLL).

The treatment goal of CLL is to improve patients' overall response rate ('ORR'), the overall survival and progression-free survival, without compromising their quality of life. A clinical trial comparing the new generation BTKi with the standard of care for 652 recurrent / relapse CLL patients over the age of 18 during a median follow-up period of 29.6 months has found that:

Comparison between new generation BTKi and standard of care on recurrent / relapse CLL patients

Patients over 18	Risk of progression and death	Reduced by 35%
	Overall response rate	Increased by 9.3%
	Cardiac side effects	Reduced by 8.3%
	Off-target effect	Fewer
	Treatment discontinuation	Less
	Heart diseases incidence rate	Lower
High-risk patients over 18	Risk of progression and death	Reduced by 47%
	Overall response rate	Increased by 9.3%

Another clinical trial comparing the new generation BTKi with chemoimmunotherapy for 479 previously untreated CLL patients over the age of 65 or patients with comorbidities between ages 18 and 65 during a median follow-up period of 26.2 months has found that:

Comparison between new generation BTKi and chemoimmunotherapy for previously untreated CLL patients

Risk of progression and death	Reduced by 58%

Mike Cheung, Founder of Cypress Charitable Trust, said, "CLL, a generally incurable and slow-growing blood cancer with higher incidence among adults aged over 50, demands a nuanced approach to treatment. The option of continuous therapy, which the new generation BTKi can provide, is equally critical. Like many cancers, CLL has the potential to develop resistance to treatment. Continuous therapy options can be vital for patients who have developed resistance to initial treatments, for whom time-limited therapy is unsuitable, or for those who are able to maintain a regimen that suits their lifestyle and preferences without undue interruption. Therefore, we urge the Hospital Authority to include the new generation BTKi in the formulary with safety net coverage, ensuring that all patients, regardless of their unique clinical circumstances, have access to the best possible care."

Dr. Herman Liu, Haematologist, said, "In 2021, 721 new cases of leukaemia were recorded in Hong Kong, while incidence rates per 100,000 persons was 6.5, both showing an upward trajectory. Although the incidence rate of CLL is lower among Chinese, its biology, genetics, and treatment outcomes in Hong Kong patients have not been fully studied. It should be noted that clinical manifestations of CLL are

diverse. Most CLL patients are asymptomatic at diagnosis and are only diagnosed from routine blood tests. The new generation BTKi can prolong both overall survival and progression free survival, has 8.3% fewer cardiac effects and less treatment discontinuation, which would make a significant difference in improving patients' quality of life. Compared with the standard of care, the new generation BTKi also lowers the risk of progression and death by 35% and 47% for all patients and high-risk patients, respectively."

CLL is a type of leukaemia, accounting for 25% of all leukaemia. It is caused by malignant B lymphocytes occupying the middle of the bone marrow, then spread from the bone marrow to the blood. The malignant B lymphocytes take up the space for the growth of healthy red blood cells, white blood cells and platelets in the bone marrow, causing anaemia and easy bleeding. Common CLL symptoms include swollen lymph nodes in the neck, underarms, and stomach, the feeling of fullness in the stomach, pain or swelling under the ribs, physical weakness and chronic fatigue, fever and prone to infections, night sweats, bruising, and weight loss..

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